A Comparison of Airway Devices for the Simulated Entrapped Patient

by

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- I have followed the required conventions in referencing the thoughts and ideas of others.
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ABSTRACT

Introduction: Control over the patient bears time-critical importance in emergency medicine. In the entrapment situation after a Motor Vehicle Collision (MVC), emergency care including airway management may need to be initiated before extrication and thus with restricted access. **Objective:** This manikin study aimed at answering the question of which advanced airway device can be inserted the fastest and most reliably by paramedics in the simulated entrapped patient. **Methods:** Paramedics were asked to insert four airway devices (endotracheal tube with the Macintosh laryngoscope, endotracheal tube with the Airtraq® optical laryngoscope, Laryngeal Mask Airway - Supreme™, and Laryngeal Tube Suction - Disposable™) in randomised order into a manikin seated in the driver seat of a light motor vehicle. Time to first successful ventilation and number of attempts required for successful insertion were measured. Following each insertion, participants were asked by means of a questionnaire to rate the degree of insertion difficulty (scale 1 – 10) and provide reasons for this rating. Finally, participants were asked which device they preferred and why. **Results:** Prospectively collected data from 26 paramedics were analysed. The LMA-Supreme™ had the shortest mean time to first successful ventilation (16.7 seconds (CI [0.95]; 14.9 - 18.6)), followed by the LTS-D™ (19.4 seconds (CI [0.95]; 18.0 - 20.8)), ETI using the Macintosh laryngoscope (37.7 seconds (CI [0.95]; 31.8 - 43.5)) and ETI using the Airtraq® (41.2 seconds (CI [0.95]; 36.7 - 45.6)). Both face-to-face ETI with the Macintosh laryngoscope and the insertion of the LMA-Supreme™ had 100% first-attempt success. Five participants required a second attempt to successfully intubate the manikin using the Airtraq® and one participant had to re-insert the LTS-D™ for correct placement. In terms of insertion difficulty, the LMA-Supreme™ received the lowest mean score (1.7/10 (CI [0.95]; 1.2 - 2.1)) followed by the LTS-D™ (2.5/10 (CI [0.95]; 1.8 – 3.2)), face-to-face ETI using the Macintosh laryngoscope (3.7/10 (CI [0.95]; 2.9 - 4.5)), and ETI with the Airtraq® (4.5/10 (CI [0.95]; 3.7 - 5.3)). Most participants chose the Macintosh laryngoscope for ETI as their preferred device (10/26; 38%) followed closely by the LMA-Supreme™ (9/26; 35%). These participants stated clinical experience and ease of insertion respectively as the primary reasons for their preference. **Conclusion:** Besides ETI, Supraglottic Airway Devices are beneficial alternative airway devices to be considered by paramedics in the entrapped patient after a MVC. The LMA-Supreme™ was the fastest and least difficult airway device to insert. Face-to-face endotracheal intubation with the Macintosh laryngoscope remains an important definitive airway that was shown to be performed competently by participating paramedics. The Airtraq® can be used for face-to-face ETI and enables improved laryngoscopy.

Key words: *prehospital emergency medicine; airway; medical rescue; entrapment-trauma; face-to-face endotracheal intubation; Airtraq; Laryngeal Mask Airway - Supreme; Laryngeal Tube Suction - Disposable.*

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ABBREVIATIONS/TERMS

Abbreviation/Term	Definition/Explanation
BLOEM	**Begin Laryngeal Optimal External Manipulation:** An acronym similar to BURP (Backward Upward Rightward Pressure) referring to manoeuvring the larynx to optimise laryngoscopy. BLOEM recognises that best view may not necessarily be achieved by backward upward rightward pressure.
CLG	**Cormack-Lehane Grade:** A widely accepted four-level scale used to grade the visualisation obtained during laryngoscopy.
DFI	**Drug Facilitated Intubation** (also *Drug Assisted Intubation* (*DAI)*): A similar process to RSI, however, commonly a less potent induction agent is used and no paralytic agent is administered.
Entrapment-Trauma	A term used in prehospital emergency medicine for MVC patients suffering injury and unable to be immediately removed from the motor vehicle.
ETI	**Endotracheal Intubation** (also often referred to as simply *Intubation*): The insertion of an airway catheter most commonly through the mouth into the trachea.
LMA	**Laryngeal Mask Airway:** A device for maintaining a patent airway, consisting of a tube connected to an oval inflatable mask that seals the larynx.
MVC	**Motor Vehicle Collision** (also *Motor Vehicle Accident (MVA)* or *Road Traffic Accident (RTA)*): occurs when a road vehicle collides with another vehicle, pedestrian, animal, or other obstacle.

NCT	**New Car Technology:** The construction advances found in modern vehicles.
RSI	**Rapid Sequence Intubation:** The administration of a potent induction agent followed immediately by a rapidly acting neuromuscular blocking agent to induce unconsciousness and motor paralysis for tracheal intubation (Walls, 2008:23).
SAD	**Supraglottic Airway Device** (also *Extraglottic Airway Device (EAD)*)**:** An airway device that is designed to rests in the pharynx (oro- and/or laryngopharynx) and does not protrude through the glottis into the trachea.

CHAPTER 1 - INTRODUCTION TO THE RESEARCH

1.1 Introduction

Chapter one introduces the reader to the research topic by highlighting the importance of airway management in emergency medicine and outlining challenges of applying these interventions in the entrapped patient after a motor vehicle collision (MVC). This information forms the foundation for the research purpose, the main research question and the objectives. Attention is then drawn to the rationale of the research and the chapter ends with clarification of assumptions and delimitations.

1.2 Background to the Research Topic

1.2.1 Anatomical and Physiological Basis

In order to maintain normal functioning, most tissues of the human body demand a continuous supply of oxygen for energy production through the oxidative degradation of nutrients. Carbon dioxide is formed as a by-product during this aerobic metabolism and must be eliminated from the human body (Levitzky, 2007; Faller, Schünke & Schünke, 2004:334). The uptake of oxygen and expulsion of carbon dioxide is the primary function of the respiratory system. The respiratory system is composed of the conducting airways, the lungs and the parts of the central nervous system concerned with the control of the muscles of respiration (Levitzky, 2007). Airway management may be defined as the interventions that provide a free and clear passageway to facilitate airflow through these conducting airways of the respiratory system (Gregory & Mursell. 2010:2).

1.2.2 Airway Management in Emergency Medicine

Patients suffering critical illness or injury frequently lose the ability to maintain a patent upper airway, thereby compromising ventilation and oxygenation. Hypoventilation and especially apnoea are some of the fastest ways to produce hypoxia and subsequent irreversible hypoxic brain injury or death (Farmery & Roe, 1996:284). Attempting to stabilise a patient is futile if airway patency and oxygenation cannot be achieved and maintained. In their case review of 2 594 deaths in a mature trauma system, Gruen and colleagues (2006:371) found failure to successfully intubate, secure or protect the airway as one of the leading errors in the care of trauma patients. Not only are hypoxia and hypoventilation common injury-related causes of mortality, they additionally represent some of the most common causes of *preventable* mortality following injury (Toschlog, Sagraves & Rotondo: 2008:185).

Airway management is thus one of the defining skills of emergency medicine that demands competency in time-critical clinical decision making and often life-saving interventions from the emergency physician, paramedic, or other healthcare provider. (Clancy, Nolan & Benger, 2008:1; Kovacs, *et al*., 2005:11-12; Walls, 2008:2). An awareness of the fundamental differences between airway management in emergency medicine as opposed to that provided in anaesthetic practice is imperative for the understanding of this specific subject matter. Table 1-1 therefore highlights important considerations in emergency airway management.

Table 1-1: Important considerations in emergency airway management (from Kill & Kratz, 2010:530-531)

- Evaluation of the airway is usually not at all or only incomprehensively possible.
- The timing of when airway interventions are required is dictated by the patient's condition.
- Expert assistance is frequently not available in the prehospital environment and may be equally limited in the hospital setting.
- The indication for definitive airway management or rather intubation often arises during progressive hypoxia and thus the ability to preoxygenate the patient may be limited.
- Many patients are haemodynamically compromised.
- It must be presumed the patient has a full stomach.
- The setting in which airway interventions need to be performed, seldom allows for optimal positioning of both the patient and the healthcare provider. This is especially true for the prehospital environment and most challenging in the entrapped patient.

1.2.3 Airway Management in Entrapment-Trauma

1.2.3.1 MVC-Related Morbidity and Mortality

The recent Global Status Report on Road Safety by the World Health Organisation (WHO) (2009:ix) states that internationally over 1.2 million people die each year from injuries due to road traffic accident, and between 20 and 50 million suffer non-fatal injuries. WHO predicts that road traffic injuries will rise from being the ninth leading cause of death in 2004 to become the fifth leading cause by 2030 (from 2.2% to 3.6% of all causes of death) (2009:ix). South African statistics vary: According to WHO, South Africa suffered a total of 14 920 road traffic fatalities in 2007, 57% (8 504) of which were motor vehicle occupants (drivers 25%, passengers 32%) (World Health Organisation, 2009:192). A further 219 978 non-fatal road traffic injuries occurred according to the same report. In their latest account on mortality and causes of death, Statistics South Africa details a total of 5 785 deaths due to transport accidents in 2008 (2010:36). Despite these variations, statistics indicate that motor vehicle collisions are a common encounter to South African Emergency Medical and Rescue Services.

1.2.3.2 Entrapment-Trauma

High-speed collisions can produce significant mechanical damage to the vehicles involved and are likely to entrap the front occupants (Morris, 2009:45-46). The term 'entrapment-trauma' has established itself to describe this patient collective in prehospital emergency care (Westhoff, *et al*. 2007:246).

South African statistics on entrapments after MVC have not been published. Wilmik and colleagues (1996:21-25) reported on 737 MVC attended by the Royal London Hospital Helicopter Emergency Medical Service (HEMS). Twelve percent of all incidents involved entrapments. The average entrapment time was 44 minutes (Wilmik, 1996:21). More recently, in their report of investigations into motor vehicle collisions with entrapment in Germany, Westhoff, *et al*. (2007:246) estimate that, considering the increasing number of motor vehicles on roads, emergency care personnel can anticipate patients that cannot immediately be extricated in approximately 15-20% of all calls to MVCs. In a further article, Westhoff and co-authors (2008:155) report on 359 entrapped motorist cases within Hannover's HEMS covering a radius 50-70 km. Eighty-six percent of all patients were drivers; the average entrapment duration in this system was 17 minutes; and 11.1% of all patients required intubation before extrication from their vehicles (Westhoff, 2008:155-159).

Even though various factors such as prolonged response times especially in the rural setting in the South African context need to be considered when extrapolating from the researcher's findings, the literature puts the incidence and circumstances of motor vehicle entrapments into relative perspective.

1.2.3.3 The Airway Challenges in Entrapment-Trauma

The seated position of the patient and restricted access while still in the vehicle may make basic airway management with bag-valve-mask (BVM) ventilation and endotracheal intubation (ETI) difficult. This may potentially result in harmful delay or even failure to provide sufficient oxygenation and ventilation. A case series in the United Kingdom by Hulme and Perkins (2005:743) revealed frequent (27%) need for a rescue airway device after failed ETI in the entrapped patient. It follows that, if the necessity to secure the airway arises while still in the entrapped situation, then alternative intubation devices or intermediate supraglottic airway devices (SADs) may need to be considered in an effort to prevent or reverse hypoxia.

1.2.4 The Research Question

This research focused on optimal care for the entrapped patient after a MVC. It was aimed at answering the specific question of which advanced airway device can be inserted the fastest and most reliably by paramedics in the simulated entrapped patient (*Figure 1-1*).

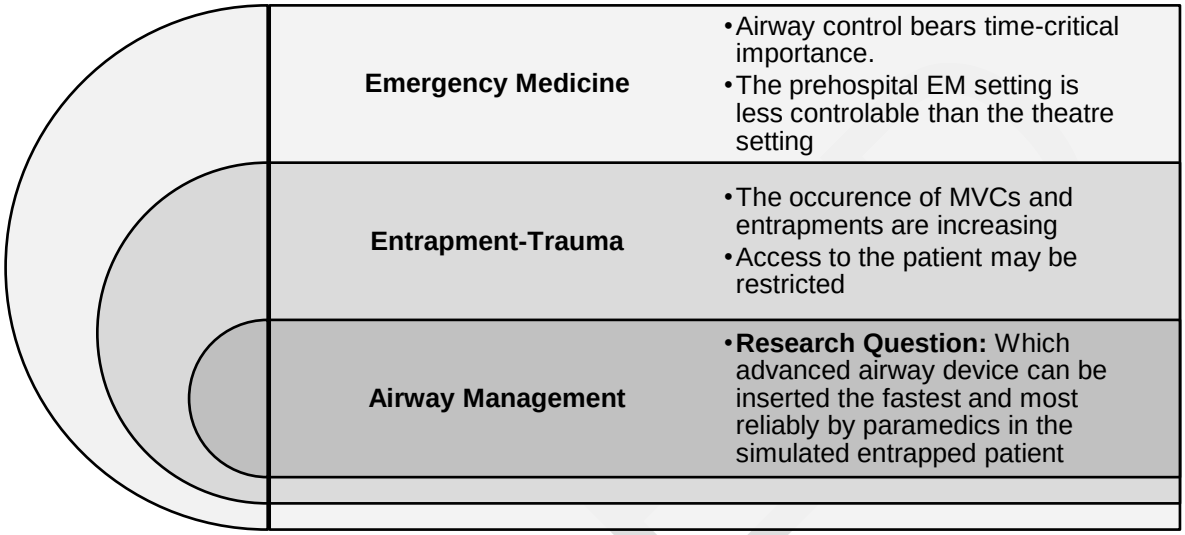


Figure 1-1: Field of study, key considerations, and research question

1.3 Research Purpose

The purpose of this research was to assess and compare the time to first ventilation, placement success and perceived difficulty of insertion of four advanced airway devices in the simulated seated entrapped patient with restricted access. Furthermore, the participants' preferences and reasons thereof were sought as this has influence on reliability of a device. The four devices under investigation were:

- An endotracheal tube inserted with the Macintosh laryngoscope,
- An endotracheal tube inserted with the Airtraq® optical laryngoscope,
- The Laryngeal Mask Airway - Supreme™ (LMA-Supreme™), and
- The Laryngeal Tube Suction - Disposable™ (LTS-D™)

Ultimately the aim of the study was to identify a fast and reliable advanced airway device that can be inserted by paramedics in the seated entrapped driver with access only through the driver's door.

1.3.1 Research Question

The research question was:

> Which advanced airway device can be inserted the fastest and most reliably by paramedics in the simulated entrapped patient?

1.3.2 Research Objectives

The research objectives were to:

- determine which airway device has the shortest time to successful ventilation in the simulated entrapped patient with restricted access.
- determine which airway device has the highest success rate (i.e. attempts required for correct placement) in the simulated entrapped patient with restricted access.
- determine which airway device is perceived to be the least difficult to insert in the simulated entrapped patient with restricted access.
- correlate rated degree of difficulty with time and success rate.
- analyse the perceptions participants have about the airway devices used in the simulated entrapped patient with restricted access.

1.4 Rationale for the Study

1.4.1 Need for the Investigation

Endotracheal intubation is the gold standard in definitive airway management. This airway is traditionally placed with a laryngoscope, in South Africa most commonly fitted with a Macintosh blade when managing the adult patient. The success rate of prehospital endotracheal intubation varies greatly depending on several factors including qualification and experience of the intubator, patient characteristics, and intubation method, i.e. Rapid Sequence Intubation (RSI) vs. Drug Facilitated Intubation (DFI) (Russo, *et al*., 2010:929-939). The incidence of failed intubation may be especially high in the entrapped patient (Hulme & Perkins, 2005:743). Leading emergency airway management courses advocate the availability of an alternative to the standard method of intubation. In their AIME (Airway Interventions and Management in Emergencies) course manual, Kovacs and co-authors (2005:54) contend that in addition to a bougie, during each and every intubation attempt, equipment for an alternative intubation technique should be prepared and available for immediate use. The use of videolaryngoscopy not only as an alternative after failed ETI by traditional means but also as an optimal primary method is advocated in current discussions on prehospital difficult airway management (Hossfeld, Lampl & Helm, 2011:4).

The entrapped patient with restricted access presents an anticipated difficult airway scenario. The immediate use of an alternative such as an indirect laryngoscopy device as best first attempt in the entrapped patient has been suggested by previous research findings (Nakstad & Sandberg, 2009:1257-1261). The Airtraq® optical laryngoscope potentially presents a cost-effective, single-use device for prehospital practitioners.

Modern SADs may deserve more recognition with regards to airway protection capability than the standard laryngeal mask airway (LMA) without gastric drainage was able to gain in emergency medicine. SADs should possibly be considered not only as rescue devices but also intermediate alternative airway devices, especially in situations when insertion time may have influence on patient outcome. As an intermediate airway device, they would provide better airway control than basic interventions until definitive airway management can be applied. The LMA-Supreme™ and LTS-D™ are both cost-effective, disposable options for Emergency Medical Services (EMS) use.

Currently few South African paramedics carry alternatives to the Macintosh laryngoscope (see 2.2.2 Paramedic Airway Management). There is thus a need to investigate realistic options for this situation and create awareness amongst the South African as well as international EMS community.

1.4.2 Lack of Current Evidence

International research in the field of emergency airway management and published literature is rich. Studies ranging from large scale clinical trials to small scale manikin studies have compared airway techniques and devices. The issue of which airway device would best serve the entrapped patient has yet to be adequately investigated. With no previous study comparing the specific airway devices in the entrapped patient scenario and incorporating South African paramedics and their perceptions, the findings of this research contribute to evidence-based medicine and provide informed recommendations for prehospital care and especially South African EMS.

1.4.3 Use of Findings

The findings of this research may be used to make recommendations to South African EMS for their standard operating procedures, the Health Professions Council of South Africa for guidelines and protocols, as well as education and training institutions for course syllabi.

1.5 Assumption and Delimitations

1.5.1 Assumption

The answering of the research question was performed with the following assumption:

- Aspiration, although an important consideration, has lesser priority than establishing a clear airway to facilitate oxygenation and ventilation.

1.5.2 Delimitations

The answering of the research question was performed within following boundaries:

- The patient was simulated to have absent airway reflexes.
- Entrapment scenarios and access angles may vary. This research focused on the entrapped driver where access to the airway was limited to that from the front of the patient through the driver's door (right).
- Prehospital care is provided by professionals with various qualifications. The participants of this research were paramedics only and were, at the time of data collection, operational in the Western Cape, South Africa.
- There are numerous direct and indirect laryngoscopes as well as SADs. This research assessed the above mentioned devices only.

1.6 Overview of the Research Report

This research report is divided into six chapters. Chapters one to four provide the reader with an introduction to give background to the research project, a portrayal of the study environment to establish knowledge of important surrounding subject matter, a review of literature with focus on the airway devices, as well as a detailed exploration of the research design and methods. Chapters five and six of the report present the findings by laying out results of the data analyses. This forms the basis for the subsequent interpretation and discussion as well as the study's final conclusion and recommendations.

CHAPTER 2 - ENVIRONMENT OF THE RESEARCH

2.1 Introduction

This chapter is intended to provide the reader with background knowledge on the surrounding in which this research is set. Its aim is for the reader to take cognizance of relevant considerations necessary for meaningful comprehension of the research findings and discussion. The chapter starts with a brief explanation of what the field of medical rescue in general entails. This section then moves on to concentrate on the discipline of motor vehicle extrication and makes the reader aware of the challenges that New Car Technology (NCT) poses to the rescue process. An introduction to the South African prehospital emergency care arena is subsequently presented. This familiarises the reader with the South African EMS system, training, and some of the circumstances in which South African EMS operates.

2.2 Medical Rescue Considerations

2.2.1 Medical Rescue

Rescue, in this context, is the process of disentanglement or otherwise freeing someone from entrapment and medically stabilising that person for transport to safety (Goodson, 2005:353). The organised effort of saving another person's life has been in existence since historical times. Modern technical rescue, however, as professional and highly skilled operations, developed only in the second half of the twentieth century. Advancements in technology (including the number of vehicles on roads), urbanisation, and an increasing number of disasters, both natural and man-made, are just some of the realities of the twenty-first century that have increased the need for specialised rescue capabilities (Rhea & Rousseau, 2010:3).

Generally all rescue operations can be divided into four main phases easily remembered by the LAST mnemonic: Locate, Access, Stabilise, Transport. In order to optimise patient outcome, medical care and technical rescue need to be simultaneous efforts. This means that medical specialists in the field of prehospital emergency care have to be part of the rescue team during training and real incidents, and that rescue efforts should be patient-orientated, rather than purely disentanglement-orientated. In other words, patient management should ideally begin as soon as access is gained. The patient's condition and medical needs should have significant weight in dictating extrication technique and timing. The term *medical* rescue recognises this critical concept.

Depending on the type of incident and environment, medical rescue can be divided into specialities or disciplines, with motor vehicle rescue (or motor vehicle extrication) being one of these. *Table 2-1* lists the medical rescue disciplines commonly taught at South African tertiary education institutions and ambulance training colleges. Many of these disciplines may, depending on specific situations, require aspects of other disciplines. Thus, motor vehicle extrication may require skills and knowledge of the Fire Search and Rescue, Hazardous Material Rescue, and Rope Rescue disciplines.

2.2.2 Motor Vehicle Extrication and The Conflict between Safety and Accessibility

Motor vehicle extrication may be defined as the safe and effective removal of a vehicle from around a patient or patients to facilitate their safe release. With the number of vehicles having increased drastically throughout the world over the past decades, motor

vehicle extrication has become one of the most commonly required rescue disciplines. The majority of MVCs with entrapment involve light motor vehicles (Morris, 2003:51). The process of motor vehicle extrication consists of several phases systematically applied and adapted to each unique situation. After the scene and vehicle or vehicles have been stabilised, the patient needs to be accessed and emergency care initiated. Subsequently the extrication commences. The tools used for vehicle extrication techniques include hand-tools, pneumatics and, most routinely, hydraulic power tools. Hydraulic power tool are used to cut, spread, squeeze, pull and push the vehicle material and are thus the key equipment used in motor vehicle extrication (*Picture 2-1*).

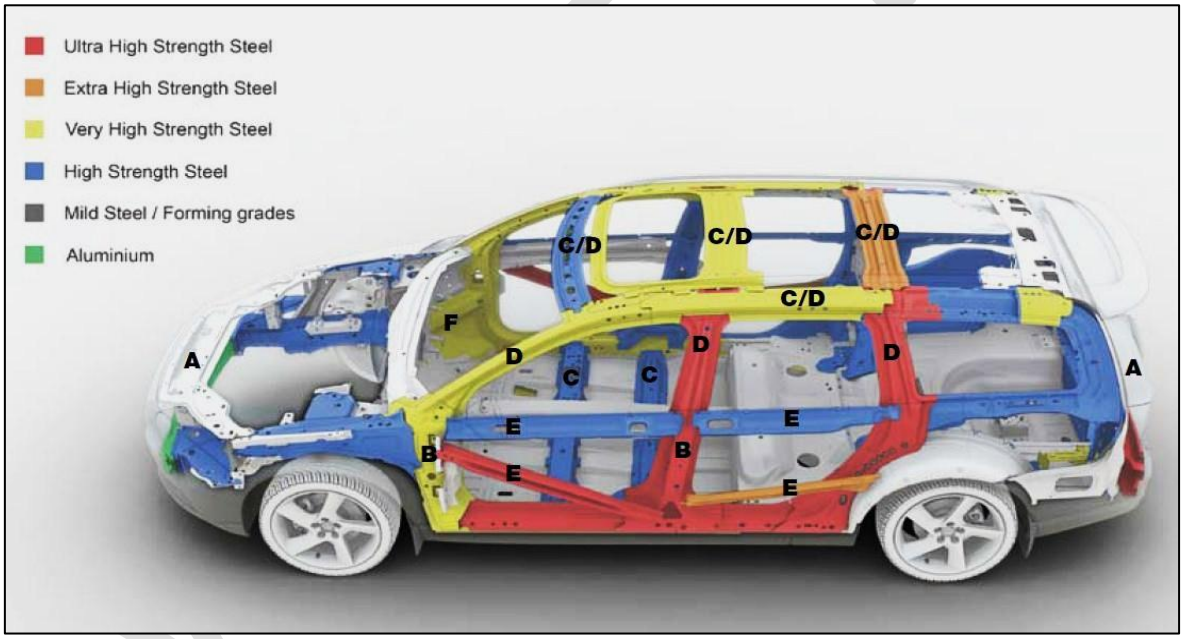
These very materials, however, serve to protect the occupants of a motor vehicle during a collision. In order to optimise this protection, car manufacturers continuously invest in NCT, i.e. the application of stronger materials, reinforced constructions (*Picture 2-2*) as well as advanced safety systems in vehicles (Holmatro, 2010:2). This means that the survival rate of victims of modern vehicle accidents is increased significantly. It also means that the safer vehicles get, the more difficult it becomes for medical rescue personnel to get access and extricate occupants entrapped after a collision (Holamtro, 2010:2; Moditech, 2010). Therefore, NCT causes a conflict between safety and accessibility and extrication may be prolonged, especially if older rescue equipment is utilised on strong materials. It follows that medical personnel need to be prepared to care for the entrapped patient.

Table 2-1: Medical rescue disciplines

- Rope Rescue
- Motor Vehicle Rescue
- Fire Search and Rescue
- Wilderness Search and Rescue
- Aviation Rescue
- Aquatic Rescue
    - Swift Water Rescue
    - Surf Rescue
- Industrial and Agricultural Rescue
- Confined Space Rescue
- HazMat (Hazardous Materials) Rescue
- Trench Rescue
- Structural Collapse Rescue

Picture 2-1: Motor vehicle extrication of an entrapped patient.

(With kind permission from Holmatro Rescue Equipment B.V., the Netherlands)



Picture 2-2: Stronger material and reinforced construction in New Car Technology (NCT)

(With kind permission from Holmatro Rescue Equipment B.V., the Netherlands)

A: Crumple zones commonly used in the vehicle's front and rear to absorb the energy of a crash. **B**: Door hinges and latches designed to keep doors closed during an impact. **C**: Chassis and roof structure designed to transfer crash energy around the passenger cell. **D**: High-strength steel reinforced pillars and roof structure provide structural strength to the passenger cell. **E**: Doors are reinforced with high strength steel intrusion bars to protect against side impacts. **F**: Dashboard reinforcement bars to prevent intrusion during both frontal and side impacts.

2.3 Prehospital Emergency Medicine in South Africa

2.3.1 The South African Setting

South Africa spreads across a land area of approximately 1.2 million square kilometres. Statistics South Africa (2010:3) most recently estimates the population to be 49,99 million. Gauteng is the most populated of the 9 provinces with an estimated 11,19 million inhabitants (22,4%). The Western Cape has an estimated population of 5,22 million (10,4%) (Stats SA, 2010:4).

South African pre-hospital advanced life support is provided predominantly by paramedics working in both public and private EMS. The vast majority of services make use of a two-tiered system with basic and intermediate life support qualified personnel on ambulances and advanced life support paramedics on response vehicles.

As in many countries, South African EMS has developed rapidly over the past few decades and is thus a relatively young profession. Short course paramedic training is conducted by several public and private training colleges and formal qualifications, namely the National Diploma in Emergency Medical Care (NDipEMC) and the Bachelor of Technology Degree in Emergency Medical Care (BTechEMC), are being offered by three Universities of Technology as well as one Comprehensive University.

Whilst services retain a degree of medical practitioner control for advice, South African paramedics work as independent practitioners within a wide scope of practice compared to international norms. (MacFarlane, van Loggerenberg, & Kloeck, 2005:146; Wallis, Garach & Kropman, 2008:70).

In the Western Cape, METRO EMS (Medical Emergency Transport and Rescue Organisation - Emergency Medical Services) provides the public emergency medical response for the rescue and transportation of the sick and injured. METRO EMS has a fleet of around 400 vehicles, including rescue vehicles, response vehicles, and ambulances (METRO EMS, 2010). Response times depend on the distance of the incident from the nearest ambulance station. Most ambulance stations have at least one light rescue vehicle, which is equipped with tools for light motor vehicle rescue incidents.

2.3.2 Paramedic Airway Management

The Advanced Life Support Protocols as stipulated by the Health Professions Council of South Africa (2006:118) include advanced airway interventions by means of ETI as well as insertion of SADs. South African paramedics are routinely issued with laryngoscopes with Macintosh blades for adult intubation. Alternative intubation devices are virtually non-existent in EMS. Therefore, when faced with the entrapped patient requiring intubation from the front, paramedics rely on the face-to-face or ice-pick intubation technique.

South African data on airway management in the entrapped patient has not been published. A recent unpublished study revealed that the majority (78.1%) of rural paramedics in the Western Cape region had been trained in the use of alternative airway devices (Cameron, 2008:10). Questionnaires completed by paramedics participating in the research revealed that restricted access was the third leading cause of difficult or failed intubation attempts. The study also indicated that only 6.2% of participating paramedics were issued with a SAD. These findings support the need for research such as this project as elaborated in chapter one.

2.4 Summary

New Car Technology creates a conflict between safety and accessibility. In the entrapment situation, emergency care may need to be initiated before extrication and thus with restricted access. Extrication may also be prolonged depending on equipment and rescue team capabilities. South African paramedics are highly trained and practice within a wide scope. They currently rely mostly on face-to-face intubation with the Macintosh laryngoscope should the need for advanced airway intervention arise in the scenario being researched.

CHAPTER 3 - LITERATURE REVIEW

3.1 Introduction

Chapter three provides an organised presentation of what has been published on the airway devices under investigation. The aim of the literature review is to convey a summary of the current knowledge on the topic to the reader. Overall, however, the literature review served a further purpose in the research process. The critical and analytical appraisal of scholarly work aided in the detailed conceptualisation of the research problem as well as the refinement of the research question. Furthermore, the literature review was used to obtain clues on the research methodology, especially data collection and analyses as advised by Brink (2007:68).

3.2 Literature Search Strategy

The purpose of the literature review was initially identified as knowledge-acquiring and guiding in building the conceptual framework and subsequently writing the research proposal. In order to reach a knowledge plateau swiftly, a systematic search strategy was utilised at the outset of the project. This search strategy is briefly outlined below. As mentioned above and illustrated in the Gantt chart (Annexure A), review of literature continued throughout the project. Up-to-date knowledge on the topic was maintained by topic-specific newsletters as well as reading new issues of appropriate scientific journals.

The literature search flow was conducted as follows:

3.2.1. Relevant books and e-books were identified in the libraries and library websites of the University of the Witwatersrand (www.wits.ac.za/library) and the Cape Peninsula University of Technology (www.cput.ac.za/library). Appropriate chapters were read and integrated into this report.

3.2.2. Electronic searches on the following databases were conducted:

3.2.2.1. McGraw-Hill's Access Emergency Medicine

3.2.2.2. EBSCOhost (Academic Search Complete)

3.2.2.3. ProQuest (Academic Research Library)

3.2.2.4. PubMed

3.2.2.5. Science Direct

3.2.2.6. SpringerLink

Words/phrases [*face-to-face intubation, reverse intubation, Airtraq, Laryngeal Mask Airway Supreme, Laryngeal Tube, airway management AND restricted access, entrapment, entrapment-trauma*] were used to search in the title field. Limitations were set depending on search engine options. Generally, limited to subscribed sources, within the professional field, and published in English and/or German language. If results were too broad, further limitations were set by adding further search words to narrow the field or by narrowing the time-frame.

3.2.3. New references that were cited as pertinent by the authors, were identified and located in reference lists of the documents obtained through steps of 3.2.2.

3.2.4. The material was read and, if considered relevant to the topic, integrated in the review.

3.3 Endotracheal Intubation

Considering the different insertion techniques of the airway devices being researched as well as the specific scenario in which they are used, i.e. the entrapped trauma patient, certain aspects of endotracheal intubation need to be reviewed briefly.

It is standard practice to use a laryngoscope with a Macintosh blade for direct laryngoscopy and insertion of an appropriately sized endotracheal tube fitted with a stylet. The aim of a technique facilitating direct laryngoscopy is to align the oral- (OA), pharyngeal- (PA), and laryngeal axes (LA) and thus provide a direct view of the glottic opening (Kovacs, *et al*., 2005:52). The alignment of axes inevitably requires movement of the cervical spine to some extent. This is an important consideration because a high index of suspicion for spinal injury exists in the patient after a MVC. Manual stabilisation of the cervical spine during the intubation will not only minimise cervical spinal movement, but also limit axes alignment negatively influencing the quality of direct view (Kovacs, *et al*., 2005:57).

The view obtained may be graded as designated by Cormack and Lehane (1984:1105), where a grade 1 view is visualisation of the entire glottic aperture; grade 2 view is visualisation of the arytenoids cartilages only or the posterior portion of the glottic aperture; grade 3 view is visualisation of just the epiglottis; and grade 4 view is visualisation of only the tongue or the tongue and soft palate. The view may be improved by the BURP manoeuvre (backward, upward, rightward pressure) on the thyroid cartilage maintained by an assistant during endotracheal intubation. Since optimising the view may not require manoeuvring the larynx in this specific directions but rather in a patient- and situation-dependent direction, the application of BLOEM (begin laryngeal optimal external manipulation) may be required (Kovacs, *et al*., 2005:76-77; Kramer, 2009). In the scenario with restricted access and associated limited number of assistants, however, this manoeuvre is likely to be difficult to perform.

3.3.1 Face-to-face Intubation

In the face-to-face intubation technique (also known as ice pick- or tomahawk-intubation) the intubator holds the laryngoscope with the right hand. An assistant maintains manual stabilisation of the cervical spine. The laryngoscope blade is inserted carefully into the mouth and advanced until the tip is at the base of the tongue. The intubator then pulls anteriorly to expose the epiglottis and glottis opening. A styletted endotracheal tube is inserted with the left hand (Chapleau, *et al*. 2008).

The less frequent use of this specific technique in combination with restricted access to a patient in whom the cervical spine needs to be stabilised is in itself considered a difficult airway situation (Murphy & Ellinger, 2008:2).

Most studies compare this technique to other airway devices. Relevant literature is therefore presented in applicable sections below. Robinson and colleagues (2004:40), however, investigated the speed and accuracy of face-to-face intubation only when compared to standard intubation in a manikin study with restricted access. The manikin was positioned supine on a stretcher inside a helicopter (BK117). Participants (flight nurses and respiratory therapists (n=21)) were timed intubating the manikin using both face-to-face and standard intubation techniques. The authors report no statistically significant difference between mean times of face-to-face (21.6 s) and standard (24.0 s) intubation (p=0.715) or number of attempts for successful intubation (1.07 vs. 1.12 respectively, p=0.581) (Robinson, Donaghy & Katz, 2004:40).

While this study indicates that face-to-face intubation is a skill that can be taught in a brief period of time and used successfully without compromise in speed and success rate (Robinson, Donaghy & Katz, 2004:40) when compared to standard technique, it provides only very limited evidence in the investigation of the scenario where standard intubation is not an option, i.e. sitting patient with frontal access only. The researchers also did not enquire about Cormack and Lehane grade or perceived ease of intubation.

3.3.2 The Airtraq® Optical Laryngoscope

The Airtraq® optical laryngoscope (Podol Meditec S.A., Vizcaya, Spain) is a single-use, anatomically shaped device for indirect laryngoscopy and endotracheal intubation (*Picture 3-1*). The device consists of two parallel channels, one housing the optical apparatus and the other functioning as a guide for a conventional endotracheal tube. A small light bulb is embedded into the distal end of the device emitting a bright light for illumination of the viewed airway structures. A heating system is integrated into the outermost lens to prevent misting. The view is transmitted through a series of lenses and mirrors to an eye-piece. An optional video system that attaches to the eye-piece is available, but not required. The Airtraq® is supplied in various sizes ranging from infant to adult.

Picture 3-1: The Airtraq® optical laryngoscope (regular/size 3) with endotracheal tube (ID 7.5 mm)

Several clinical studies in the setting of the operating room have demonstrated that the Airtraq® is easier to use and may be able to provide intubating conditions that are comparable or superior to those of the Macintosh laryngoscope (Prodol, 2010). These include studies done by Maharaj, *et al*. (2008:182-188) as well as Hirabayashi and Seo (2009:112-113). In their randomised, controlled clinical trial, Maharaj and colleagues (2008:182-188) compared the ease of intubation using the Airtraq® with the Macintosh laryngoscope in patients at increased risk of difficult tracheal intubation. The Airtraq® used by experienced anaesthetists reduced duration of intubation attempts, the need for additional manoeuvres, and the intubation difficulty score (Maharaj, *et al*., 2008:184-185). Hirabayashi and Seo (2009:112-113) evaluated the performance of the Airtraq® by novice laryngoscopists. After only a short demonstration and five to six practice intubations using a Laerdal Airway Trainer® the non-anaesthesia novice physicians used the device clinically. The Airtraq® reduced both time to secure the airway and the incidence of failed tracheal intubation when compared to the Macintosh laryngoscope (Hirabayashi & Seo, 2009:112).

The advantages of the Airtraq® over intubation with the Macintosh laryngoscope by paramedics in the prehospital setting have been demonstrated by an observational study conducted by Harvey, *et al*. (2010:S70). Paramedics with more than one year experience were given training in the use of the Airtraq®. Over a nine-month period 238 patients were intubated either by Airtraq® or by standard technique using the Macintosh laryngoscope. The decision was based on paramedic discretion. Sixty-seven (28%; CI [0.95]; 23-34%) intubations were attempted using the Airtraq® and 171 (72%, CI [0.95]; 66-77%)

intubations were attempted using standard technique. Airtraq® first pass success proportion was 51/67 (76%, CI [0.95]; 64-86%) and thus significantly higher when compared to 99/171 (58%, CI [0.95]; 65-50%) achieved with the Macintosh laryngoscope (p=0.0135). CLG 1 view was reported in 51 (76%, CI [0.95]; 64-86%) patients with the Airtraq® and only in 38 (22%, CI [0.95]; 16-29%) patients with the Macintosh laryngoscope (p<0.0001) (Harvey, *et al*., 2010:S70). The authors note that no statistical significance was detected between groups in age or the presence of trauma, c-spine, induction or CPR during intubations (p>0.05) and conclude that the Airtraq® provides higher success rates and higher proportion of grade 1 view, but also acknowledge limitations of the study by not being randomised and including only a small sample (Harvey, *et al*., 2010:S70).

Results of a manikin study comparing the Airtraq® to the Macintosh laryngoscope in a simulated difficult airway scenario were published by Woollard and co-authors (2008: 26-31). Both paramedic students and experienced prehospital practitioners participated in this study. Airway difficulty was not due to access but rather created by full spinal immobilisation on a trauma board (including cervical collar) and inflation of the manikin's tongue resulting in CLG 3 or 4 views. First-time intubation rates for the Macintosh and Airtraq® laryngoscope for students were 0/23 (0%) vs. 10/23 (44%) (44% difference, CI [0.95]; 26-63%, p<0.001) and for experienced practitioners were 14/56 (25%) vs. 47/56 (84%) (59% difference, CI [0.95]; 42-72%, p<0.0001), respectively (Woollard, *et al*., 2008:28).

Cognisant of the far more fatal consequences of missed oesophageal intubation compared to corrected failed intubation, the researchers also recorded frequency of this specific misplacement. Statistically significant differences were observed in favour of the Airtraq® (Woollard *et al*., 2008:28). Furthermore and similarly to the research performed by Hirabayashi and Seo (2009:112-113) summarised above, Wallard and co-researcher's (2008: 26-31) methodology indicates that the safe and effective use of the Airtraq® has a very steep learning curve.

The use of indirect laryngoscopy technique as best first attempt in the entrapped patient has been suggested by Nakstad and Sandberg (2009:1257-1261) when they found that the GlideScope Ranger® (video-laryngoscope), enabling statistically significantly faster intubation times in simulated patients with restricted access. In another manikin study, Hampton and colleagues (2008:S113-S114) compared endotracheal intubation by Airtraq®, GlideScope Ranger® and direct laryngoscopy in a closed space environment of a helicopter frame. The Airtraq® was found to be superior compared to both the GlideScope

Ranger® video laryngoscope and the Macintosh laryngoscope in degree of intubation difficulty (10 cm VAS means = 2.885, 3.615 (p=0.252), and 5.145 (p=0.0041) respectively) as well as intubation times (23.810s, 39.295s (p<0.0001), and 39.145s (p<0.0001) respectively). Both devices had improved CLG views compared to standard direct laryngoscopy (Airtraq® p=0.0006; GlideScope Ranger® p=0.0047) (Hampton, *et al*. 2008:S114).

The literature suggests that the Airtraq® optical laryngoscope may be an advantageous airway device in the restricted access situation, yet none of the research explored the specific scenario of a seated patient with frontal access only. Asai (2009:1114-1117) reports on a comparison of intubation using the Pentax Airway Scope® (video-laryngoscope) and the Macintosh laryngoscope in, amongst others, the simulated patient confined to a driver's car seat. The findings indicated that "in situations where access to the patient's head is restricted, the Pentax Airway Scope is more effective than the Macintosh laryngoscope" (Asai, 2009:1117). Even though the device is a different one, the many shared properties of the Airtraq® and the Pentax Airway Scope® lend themselves to draw parallels. Moreover, case studies of successful awake intubations using the Airtraq®, i.e. in the sitting patient (Gloria *et al*. 2008:247) suggest its suitability to be used in the situation at hand.

Noteworthy too is a case study by Black (2007:509-510) speaking in favour of the use of the Airtraq® in prehospital trauma patients. The case report describes the use of the Airtraq® to successfully intubate (first attempt, <20 s) a patient with traumatic asphyxia after suicide attempt by hanging. The Airtraq® was used successfully despite upper airway haemorrhage requiring frequent suctioning. Even though a case report provides poor level of evidence, this is an important observation considering the high frequency of head and thoracic trauma occurring in light motor vehicle entrapment-trauma (Ersson, Gonzales & Rutten, 2001:474; Westhoff, *et al*. 2007:250) and the concern of obstructed laryngoscopy.

3.4 Supraglottic Airway Devices

3.4.1 The Laryngeal Mask Airway-Supreme™

The Laryngeal Mask Airway - Supreme™ (LMA Company, United Kingdom) (*Picture 3-2*) is a disposable, latex-free laryngeal mask airway that combines features of other laryngeal mask airways, namely the LMA-ProSeal™ and LMA-Fastrach™. A semi-rigid elliptical tube with integrated bite block allows the device to be inserted without placing fingers in the patient's mouth. A drainage tube originates from an elongated tip that provides seal at the upper oesophageal sphincter. With the LMA-Supreme™, the manufacturer claims to "bridge the gap between laryngeal masks and endotracheal tubes" (LMA International, 2010). The LMA-Supreme™ is currently available in three sizes for children weighing 30-50 kg (size 3), adults weighing 50-70 kg (size 4) and adults weighing 70-100 kg (size 5).

Picture 3-2: The Laryngeal Mask Airway - Supreme™ (Size 4; 50-70 kg)

With ongoing debates about whether or not laryngeal mask airways have a place in emergency medicine, published clinical trials investigating the LMA-Supreme™ are exclusively from within the realms of the operating theatre at the time of this review. In this setting the device has performed to meet most demands. Tan, Chen and Liu (2010:550-554) evaluated the LMA-Supreme™ in 100 patients with normal airways having elective surgery. First attempt insertion and ventilation success rate was 96%; Second attempt success rate was 100%. Median insertion time was 15 seconds and the researchers concluded that their findings suggest that in patients with normal airways, the LMA-Supreme™ is easy to insert and provides a satisfactory airway with adequate seal pressure for ventilation. In six patients the seal pressure was, however, noted to be below

15 cmH_2O. Furthermore, the researchers expressed concern about the semi-rigid tube possibly applying pressure on the cervical spine vertebrae, mucousa and nerves (Tan, Chen & Liu, 2010:553).

Similarly Cook and colleagues (2009:555-562) evaluated the LMA Supreme® in 100 non-paralysed in-hospital patients and found it to be a reliable airway that is easily and rapidly inserted and that provides a good airway seal. They report successful insertion on first attempt in 90%, on second attempt in 9%, and on third attempt in 1%. Their median insertion time was 18 s and median airway leak pressure 24 cmH_2O. The authors note that the device may require manipulation for optimal ventilations which they found to be required in 5% of all patients (Cook, *et al*., 2009:558).

Similar results in terms of success rate and insertion time in a study by Timmerman, *et al*. (2008:970-975) in which participants had only limited experience in LMA anaesthesia, indicate that the device requires little training. Thus results indicate that the device can be used safely and effectively by medical personnel with limited clinical experience.

Providing only weak evidence but exemplifying the very situation and challenge this research looks at is a case report by Truhlar and Ferson (2008:107-108): The authors report on the successful use of the LMA-Supreme™ as the primary airway device in an entrapped patient with frontal access only. After MVC with a train the entrapped adult driver suffered polytrauma including severe maxilla-facial injuries with heavy airway bleeding. Face-to-face intubation was not attempted by the attending anaesthetist who placed a LMA-Supreme™ immediately. Insertion was successful on first attempt. Specifics about insertion time are not given. The authors claim that ventilation with a self-inflating bag was effective for 30 minutes after which the patient experienced cardiac arrest whilst still entrapped. No air-leak occurred during ventilations and the larynx was protected from airway bleeding (Truhlar & Fehrson, 2008:108).

3.4.2 The Laryngeal Tube Suction-Disposable™

The laryngeal tube (LT™) is a latex-free supraglottic airway device available in a single lumen version as well as in a dual lumen version. The Laryngeal Tube Suction (LTS™) is the dual lumen version, i.e. with a gastric drainage tube in addition to the airway tube. As a dual lumen airway device, the LTS™ is similar to the Combitube® or Easytube®, however, it lacks the integrated potential endotracheal tube and thus relies on the high likelihood of oesophageal placement by blind insertion. Furthermore, both the distal and

proximal cuffs of the laryngeal tube are inflated via only one inflation tube. The LTS-D™ (*Picture 3-3*) is the disposable variation of the LTS™. The laryngeal tube is available in a range of sizes, including paediatric sizes, except the LTS-D™ which is currently available in three adult sizes only. All laryngeal tubes are colour-coded according to their size and are supplied with colour-coded, purpose-made syringes indicating the required volume of air for each specific size.

Picture 3-3: The Laryngeal Tube Suction – Disposable™ (Size 4; 155-180 cm)

Prehospital research into the use of the LTS-D™ is more abundant when compared with the LMA-Supreme™ and it follows that extrapolation of results from research conducted within the operating theatre is not needed as much.

The time-saving benefits of using a LT™ as a SAD placed during cardiopulmonary resuscitation (CPR) instead of intubating the patient has been demonstrated (Wiese, *et al*., 2009:1-7; Wiese, *et al*., 2009:194-198). But also in patients requiring emergency airway management for other indications, the LT-D™/LTS-D™ has proven itself to be a reliable tool for prehospital airway management in the hands of both paramedics and emergency physicians (Schalk, *et al*., 2010:323-326). In their recent examination of 157 (110 cardiac arrest, 47 non-cardiac arrest) prehospital insertion attempts using the devices, Schalk and co-researchers (2010:323-326) found a 96.8% success rate with most placements being achieved in less than 45 seconds (78.9%). The majority of insertions were successful on first attempt (80.9%) despite most (61.1%) of the participating paramedics and emergency physicians having inserted the device on less than six previous occasions (Schalk, *et al*., 2010:325).

Schneller, *et al*. (2010:210-216) reflect on eight difficult airway management situations in which the LTS-D™ was successfully used either as primary or rescue device. Cases include both trauma and medical patients. Interesting to note is that even though all cases were non-entrapment situations and access to the patients was non-restricted, emergency physicians and paramedics elected to insert the LTS-D™ from the front, facing the supine-positioned patients. All insertions were completed within 30 seconds and were rated as "easy (immediate ventilation was achieved satisfactorily)" (Schneller, *et al*., 2010:215). In six out of the eight cases the airway was converted to an endotracheal tube by surgical cricothyrotomy or tracheostomy which can be performed with the extraglottic device in situ allowing for continuous oxygenation and ventilation.

Two further case reports are noteworthy: The potential consequences of not choosing a SAD with gastric drainage are illustrated by two case studies presented by Dengler and colleagues (2010:1-4) Two patients are reported on in whom prehospital insertion of the single-lumen LT™ was associated with significant pulmonary aspiration in one patient and gastric overinflation in the other. "In both cases peak inspiratory pressure exceeded the LT leak pressure of approximately 35 mbar. This resulted in gastric inflation and decreased pulmonary compliance and increased inspiratory pressure further, thereby creating a vicious circle" (Denger, *et al*., 2010:3).

A possible adverse effect of the LTS-D™ is reported by Gaither, *et al*. (2010:367-369) who noted massive tongue engorgement most likely caused by obstruction of venous drainage from the tongue by the proximal, oropharyngeal balloon of the device. This occurred approximately three hours after prehospital insertion and speaks in favour of the LTS-D™ remaining only an intermediate airway device.

When compared with other SADs the LT™ was found to have the highest success rate in a meta-analysis of literature (Hubble, 2010:515-530). The pooled success rate of the LT™ was 96.5% (CI: 71.2%-99.7 %) across all patients and clinicians. The researchers refer to a single study by Wiese, *et al*. (2009:194-198) to conclude a success rate of 99.5% (CI: 92.0%-100%) amongst paramedics (Hubble, 2010:520). The very limited number of studies concerning the LT™ in this meta-analysis is, however, a significant limitation when using results to assess this device specifically. The device was compared with several other SADs including the LMA with a pooled success rates of 87.4% (CI: 79.0%-92.8%) and 82.7% (CI: 70.0%-90.8%) across all patients and clinicians and all non-physicians respectively (Hubble, 2010:520).

LT™ insertion time was contrasted against ETI time in a manikin study by Russi, Wilcox and House (2007:263). Participants comprised a variety of healthcare providers. The researchers used two different manikins, the Laerdal AirMan® and the Laerdal SimMan® for two different scenarios. The Laerdal AirMan® was used for the simulation of a trauma patient with a cervical collar in place and no c-spine manipulation advised; the Laerdal SimMan® for a medical patient without c-spine restrictions. Even though this methodology is poor and limiting overall results, the study of the isolated trauma scenario, more crucial to this report, indicates a statistically significant time difference between LT™ insertion and ETI (26.9 s (95% CI: 24.3-29.5) vs. 76.4 s (95% CI: 63.3-89.5) respectively) (Russi, Wilcox & House, 2007:265). Furthermore, success rate in the trauma scenario was also significantly higher with the LT™ (94.4%) compared with ETI (69.4%) (Russi, Wilcox & House, 2007:265).

Finteis and colleagues (2001:327-334) found no significant difference in terms of insertion time between the LT™ and ETI in their prospective, randomised manikin study, but revealed the LT™ to be the most preferred (62.8%) and rated most easily to insert (55.8%) amongst paramedics when compared with the Combitube® and LMA.

More recently and in South Africa, Castle, *et al*. (2010:860-863) compared the LT™, Igel® (Intersurgical Ltd, Workingham, UK) and LMA in terms of insertion time and participating paramedic students' preference with reasons. With its non-inflatable mask, the Igel® was the fastest airway, followed by the LT™, and lastly the LMA. Mean insertion times were all significantly different with the LT™ and the LMA achieving a mean insertion times of 22.4 s (95% CI: 20.3-24.5) and 33.8 s (95% CI: 30.9-36.7) respectively (Castle, *et al*. 2010:861). The Igel® was by far the preferred device (63%), however, this preference appears to be based predominantly on ease and speed of insertion. Reasons given for LT™ preference (17%) demonstrated more awareness of airway protection capability.

The literature search was unable to identify case reports of the LT™ being used in a patient with restricted access. A manikin study compared the device to other airway interventions in an entrapped patient in a light motor vehicle (Golf IV) including a driver (left) situations with access through the side window (Genzwürcker, *et al*. 2007:164). Twenty-one paramedics and 17 emergency physicians participated. Further demographics are not given. The LTS-II™ was compared to the LMA-Fastrack™, Combitube® and Easytube® as well as ETI (presumably with Macintosh laryngoscope) and facemask ventilation. In the entrapped driver scenario, insertion of the LTS-II™ from the side window showed fastest time (18.8 s (11-34)) and second-best first-attempt success

rate (94.7%) (after LMA-Fastrack™ (97.4%)) (Genzwürcker, *et al*. 2007:164). The ease of insertion or other perceptions of participants was not investigated. Interesting as well is that only 21.1% of participants succeeded in facemask ventilation from the side and only 55.3% from the back seat. Gastric inflation was expectedly high during facemask ventilation and significantly reduced to 2.6% during ventilation through the LTS-II™ (Genzwürcker, *et al*. 2007:164).

3.5 Conclusion

Literature on emergency airway management including that provided in the prehospital setting is widely available and comprehensive. Literature on the airway devices and their use in the entrapped patient is far more limited. The review funnelled current knowledge from crucial and recent studies to form a concise foundation of relevant information. The search results also made clear that internationally there is a distinct lack of research into the airway devices in the entrapped patient with restricted access. This is forcing current practice into being based on extrapolation from adjacent research findings and therefore not optimally evidence-based. Moreover, the vast majority of literature stems from overseas journals, pointing to the dire need for a South African perspective on the topic.

CHAPTER 4 - RESEARCH METHODS

4.1 Introduction

This chapter is intended to outline the research design and methods. A brief elaboration on paradigm placement is followed by a clarification of the variables and research design classification. Details on data collection are given by a description of protocol followed on data collection days. Ethical issues, carefully considered during this research project, are examined. Finally, the descriptive and analytical studies performed using the obtained records and the data quality is critically appraised.

4.2 Research Design

4.2.1 Research Paradigm

This inquiry was conducted within the positivist paradigm using a multi-method approach. The reason for placing the study within this perspective is that positivist assumptions best suit the research question. To recall, the research question is:

> Which advanced airway device can be inserted the fastest and most reliably by paramedics in the simulated entrapped patient?

The fundamental assumption of positivists is that an objective reality exists that can be studied and known, and that the researcher is independent from what or who is being researched (Polit & Beck, 2006:14). The aim was to identify which of the four airway devices is the *fastest* and *most reliable*. The measurements of insertion time, success rate and rated degree of insertion difficulty, providing quantitative information used for statistical analysis, were identified as the best methods for obtaining evidence. Furthermore, the paradigm guided the methodology by suggesting control over the context and focus on the product (Polit & Beck, 2006:14).

The ultimate goal of any disciplined inquiry is to gain knowledge (Polit & Beck, 2006:17). Neglecting the participants' preferences and reasons thereof would not only have devalued the importance of the participants' professional opinions, but also hindered full understanding. Reliability is defined as the quality of being consistently good in performance, and able to be trusted (Oxford Advanced Learner's Dictionary, 1998:987). While success rate and the rated degree of insertion difficulty quantify performance, these measures may not be a true reflection of an individual's trust in a particular device. The study therefore also collected some qualitative information about the participating paramedics' perceptions.

4.2.2 Research Design Classification

This was an experimental manikin study. The three conditions as stipulated by Brink (2007:93), manipulation, control and randomisation, were all present, except for a true control group. The independent variables, i.e. the airway devices, were manipulated to assess the changes in the measured dependent variables. Table 4-1 lists the independent and dependent variables and Figure 4-1 illustrates the relationship between them. The researcher had control over the specific variables being studied and the conditions of

manipulation by the careful development of the data collection protocol described below. Furthermore, to eliminate the threat of some recognised extraneous variables, demographic information from the participating paramedics was analysed and integrated as attribute variables. Table 4-2 lists the demographic variables. While there was no true control group, participants performed the four interventions in randomised order. Table 4-3 lists descriptive information obtained from the participants' perception about the airway devices for qualitative analysis.

Table 4-1: Independent and dependent variables

Independent Variables	**Dependent Variables**
1. Endotracheal intubation with the Macintosh laryngoscope 2. Endotracheal intubation with the Airtraq® optical laryngoscope 3. Insertion of the LMA-Supreme™ 4. Insertion of the LTS-D™	1. Time 2. Success rate 3. Perceived ease of insertion

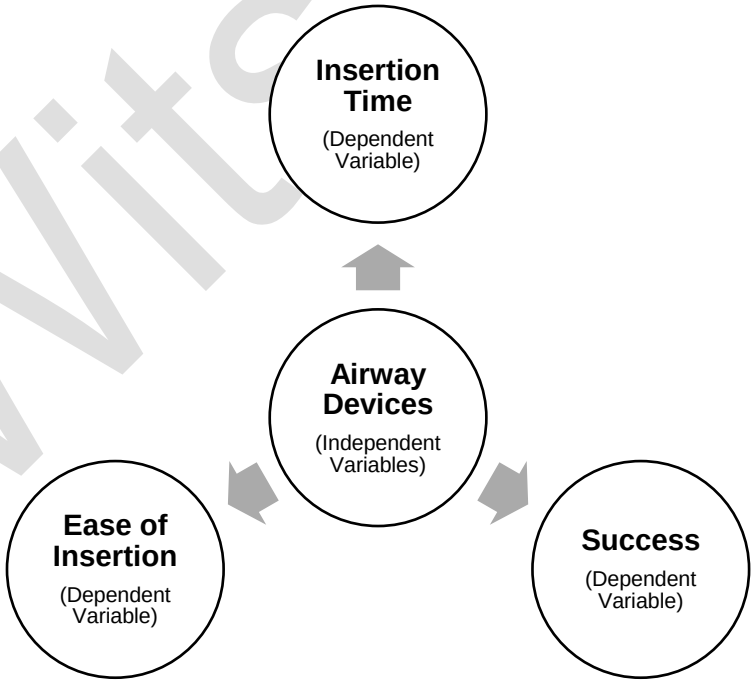


Figure 4-1: Graphical representation of multivariate relationship

Table 4-2: Demographic variables

Demographic Variables
1. Qualification
2. Exposure to the patient simulator
3. Work experience
4. Experience with airway management in entrapment-trauma
5. Exposure to airway devices

Table 4-3: Qualitative Information

Qualitative Descriptive Information
1. Reason(s) for rating
2. Preferred device and reason(s)

4.3 Data Collection

4.3.1 Sampling Strategy

The research project was advertised by means of an information letter (Annexure E) which was sent via electronic mail to paramedics from both the public and private sector in the Western Cape via the METRO EMS training college and regional managers respectively. Further announcements of the project were made at the Cape Peninsula University of Technology where paramedics from various areas and services of the Western Cape obtain further education and training by enrolment in the Bachelor Degree in Technology in Emergency Medical Care. The initial restriction of at least three years operational experience had to be lifted to achieve sufficient participation. Nevertheless, the mean operational experience of all participants remained above this initial goal (see Chapter five: Results). Convenient sampling (volunteer sample) was thus used with the researcher being well aware of the limitations this non-probability sampling strategy introduced.

Several factors needed to be considered when choosing an appropriate sample size as outlined by Brink (2007:135-137). While a larger sample size in quantitative research will in general increase accuracy of results, an accurate data collection method, as was used in this project, allows for a smaller sample size (Brink, 2007:137). The very general “10 subjects per variable” rule (Brink, 2007:136) would imply a minimum of 30 participants. By hypothesising a significant difference between the two endotracheal and the two supra-glottic techniques, however, a smaller sample size was considered to be acceptable. After consultation with the institution’s assessor group, a minimum of 20 paramedics was required for the synthesis of meaningful results.

4.3.2 Protocol

Data were collected prospectively from 30 voluntarily participating paramedics from the Western Cape region. One participant withdrew and data obtained from a further three participants were excluded from analysis due to manikin problems which made data unreliable (discussed further under 4.6 Data Quality). Data from 26 paramedics were eventually used for analysis. Relevant participant demographics were obtained by means of a questionnaire at the start of each of the four data collection days.

A training workshop on airway techniques/devices (Annexure G) was conducted prior to data collection which included theoretical and practical training on the airway devices and

their use including the specific scenario under investigation. All training was done according to manufacturers' instructions.

The entrapped patient was simulated by positioning a manikin (Laerdal ALS Simulator®, Laerdal Medical, Stanvenger, Norway) as the entrapped driver in a light motor vehicle (Hyundai Getz, 2008) during daytime (Picture 4-1). The airway of Laerdal manikins (SimMan™) has been shown to be generally acceptably realistic (Hesselfeldt, Kristensen & Rasmussen, 2005:1339-1345). The vehicle was positioned under a gazebo to eliminate weather variables. Normal amounts of airway secretions were simulated with Laerdal airway manikin lubricant and kept constant throughout data collection. All airway devices were lubricated before insertion procedures. One assistant maintained consistent cervical spine immobilisation from behind the patient as required by standard trauma protocols. The cervical collar was removed as a standardised practice during the airway interventions. The assistant was not permitted to apply BLOEM or any other manoeuvre to potentially improve laryngoscopy or airway device insertion. Access was limited to that from the side-door (right) and facing the patient. The paramedics were individually asked to establish an advanced airway by using the following devices in randomised order.

1. Face-to-face ETI with a laryngoscope with Macintosh blade (endotracheal tube ID 7.5 mm)
2. Face-to-face ETI with the Airtraq® optical laryngoscope (Prodol Meditec S.A., Spain) (Size 3, endotracheal tube ID 7.5 mm)
3. Insertion of the Laryngeal Mask Airway Supreme™ (LMA Company, United Kingdom) (Size 4)
4. Insertion of the Laryngeal Tube Suction Disposable™ (VBM Medizintechnik GmbH, Germany) (Size 4)

Time was measured with a stop watch from end of BVM ventilation to first bag-tube ventilation (BTV) and recorded with a camera (QuickCam®, Logitech) mounted inside the vehicle on the rear-view mirror. Successful placement was assessed by visual inspection of airway placement after the timed scenario and recorded as the number of attempts for each device. A maximum of three attempts were allowed per device. One attempt started at the end of the last BVM ventilation and was allowed to continue for a maximum of 120 seconds after which the participant was stopped and the attempt was recorded as unsuccessful. Degree of difficulty was measured on a questionnaire using the Cormack-Lehane grading system for both ETI devices and a 1 to 10 rating scale for all airway interventions. Participant completed the relevant page immediately after using each

device. The questionnaire also enquired about the individual participant's perceptions about the degree of insertion difficulty as well as personal preference and reasons thereof. This was done by multiple choice options which represent pre-defined themes as well as blank spaces for the participants' own responses. A separate data collection sheet was used by the researcher to record time and number of attempts required for successful insertion. Each participant was directed to leave the data collection area immediately after completion.

Picture 4-1: The Laerdal ALS Simulator™ manikin positioned in the car (Hyundai, Getz)

4.4 Ethical Considerations

4.4.1 Participation

The Human Research Ethics Committee of the University of the Witwatersrand granted ethical approval for this research (Annexure B). All participants were informed in writing and verbally about details of the workshop, data collection and the research project overall. Contact details of both the research supervisor, Dr C. van Loggerenberg as well as the University of the Witwatersrand Research Ethics Office were made available to participants to contact if they had any concerns or complaints. Participation was voluntary and was allowed to be discontinued without prejudice at any time. All participant signed informed consent forms (Annexure F).

4.4.2 Confidentiality

Participants were informed that absolute confidentiality cannot be guaranteed. However, every effort was and is being made to maintain confidentiality. Participants' names were not used on any of the data collection sheets. A number was allocated to each participant for individual result and video tracking if required. Individual results, including video footage, are kept safe and confidential and are not made available to anyone without the written permission of the individual participant. An electronic database of records has been established and is being kept in a password protected file accessible only by the investigator or persons who have been granted access from participants. Data will be stored indefinitely for the researcher's academic records and in a safe place. Electronic formats are safeguarded by passwords.

4.5 Data Analysis

4.5.1 Quantitative Data

Quantitative data were analysed using Stata™ 10.0 statistics/analysis software by StataCorp® (Texas, USA). The data analyses for this study were performed in three phases. Firstly, descriptive statistics were computed for all variables of interest. Comparative box plots were also created to assist in the analysis and illustration of results. Secondly, Shapiro-Wilk tests were conducted for normality on all relevant variables. This informed statistical test choice for both the univariate and multivariate analysis. Due to the distribution characteristics of the data, non-parametric statistics were used, namely Kruskal-Wallis for the analysis of variance and Wilcoxon rank sum (Mann-Whitney U) and Chi Square tests (nominal variables) to conclude testing for statistical significance between individual variables. The level of statistical significance (alpha) used was .05. Thirdly, relationships between variables were tested using Spearman's rho and Multiple Regression analysis. Multiple Regression was performed using automatic forward stepwise models to examine relationships between three or more variables while Spearman's rho was used when testing relationships between only two variables.

4.5.2 Qualitative Data

Participants' statements were merged with pre-defined themes or used to create further themes. The themes were verified through reflection and discussion by the researcher and supervisor. The refined responses are presented and examined in the following chapters.

4.6 Data Quality

This section briefly clarifies equipment problems and factors affecting validity and reliability and how they have been controlled in pursuit of meaningful research findings reflecting reality as accurately as possible.

4.6.1 Equipment Failure

Equipment failure occurred in three of the participating paramedics. The simulated airway anatomy deformed during endotracheal intubation attempts significantly prolonging placement or prohibiting tube advancement alltogether. This occurred during the first three participants and the manikin was subsequently exchanged for another, identical but non-problematic Laerdal ALS Simulator™. This specific second manikin served for all other data collection without interference. The participants who encountered the manikin problems were not allowed to re-participate, as this would have influenced reliability due to extra experience with the devices compared to the standardised experience gained during the workshop.

4.6.2 Validity and Reliability

4.6.2.1 Threats to Internal Validity

In the assessment of the four airway devices, the professional participants may be considered as human instruments. As such, the participants may have gained skill on the manikin during data collection over and above the standardised workshop experience, which possibly could have influenced measured variables. Randomisation of the sequence in which the airway devices were used counteracted this threat. Furthermore, it should be noted though that data collection of this study took place over a short period of time per participant.

4.6.2.2 Threats to External Validity

Both test anxiety and the Hawthorne effect were recognised reactive effects posing threats to external (and internal) validity. The participants were informed comprehensively about the research and thus were aware that their expert skill and opinion was sought to evaluate the airway devices. No persons other than those directly involved in the data collection, i.e. the researcher and assistant, were permitted to observe the proceedings. This lessened any anxiety participants may have felt. The Hawthorne effect remains an acknowledged possible limitation of the data collection methods and thus the research output. It must be noted, however, that paramedics are commonly trained in the simulated setting and video recorded for examination purposes. Furthermore, paramedics are routinely practicing in the eye of public bystanders and it can be argued that this

accustoms the paramedic to work while being observed. The camera was not be moved or operated by an active camera-man in an effort to make it least concerning to the participant. Video recording also contributed to an unobstructive technique by allowed the researcher to maintain a distance during data collection and in this way decreased possible researcher effect. Volunteer bias introduced by the volunteer sampling strategy as well as the limited sample size were recognised as the most significant threats to external validity and are further discussed under in chapter six.

4.6.2.3 Reliability

Three measurement instruments were used to collect quantitative data in this research project, namely the stop watch to measure time, the visual assessment of device placement to evaluate success, and the questionnaire filled in by the participants to assess degree of difficulty (CLG and 1-10 scale). The same stop watch was used and the same person timed and assessed device placement for all data collection. Both these measurements were considered very reliable, stable as well as internally consistent.

Both, the questionnaire on the airway devices as well as the questionnaire on paramedic demographic information, were comprehensively and consistently explained to the participants and any uncertainties were explained. This measurement too was considered to be reliable, stable and internally consistent.

4.6.3 Trustworthiness//Transferability

The methods for establishing validity and reliability in the qualitative paradigm differ to those of the quantitative research. Nevertheless, the rigour of qualitative data still needs to be appraised (Brink, 2007:118). After analysis and discussion of the participants' responses the findings were considered credible to the participating paramedics and acceptable as an authentic portrait of their perceptions. Similarly to the limitations that the sample size introduced to generalisation of quantitative results, the sample size also limits transferability of qualitative findings. The findings have to be considered in light of the limited number of volunteering paramedics from the Western Cape.

In this study, comparison of data obtained over the four data collection days showed consistency. The unswerving adherence to the workshop plan and testing procedures resulted in a habitual data collection atmosphere and reduced the likelihood of measurement error in terms of the participants' responses

4.7 Conclusion

The proposed research protocol was followed very closely and only minimally adapted to unforeseen challenges in areas where flexibility allowed for such deviations. The implemented process produced the raw data in an ethical and confidential manner that was consumed for the proposed analysis within recognised limitations. The research techniques were critically appraised by the supervisor as well as the research proposal assessor group of the University of the Witwatersrand's Division of Emergency Medicine and found adequate in terms of validity, reliability and trustworthiness.

CHAPTER 5 - RESULTS

5.1 Introduction

This chapter lays out the main research findings following the data analyses as described in chapter four. Tables, graphs and outcomes of statistical tests performed are presented to aid the reader in understanding the data. Details on statistical tests used, as well as the value of the calculated statistic and its significance are also provided. This is followed by a brief description of dominant themes that emerged from the qualitative responses obtained.

5.2 Quantitative Results

5.2.1 Descriptive Statistics

Descriptive statistics are tabulated in Table 5.1 below. The following sub-sections present these descriptive statistics as well as statistical tests performed as described in chapter four.

Table 5-1: Descriptive Data

	Mean	Median	Standard Deviation	95% Confidence Interval
Operational paramedic experience (months)	38.8	23.0	43.4	22.1 - 55.5
Estimated entrapment-trauma airway management (no./year)	4.3	3.5	3.8	2.8 - 5.8
Time to first successful ventilation (seconds)				
Macintosh	37.7	33.5	14.4	31.8 - 43.5
Airtraq®	41.2	39.5	11.0	36.7 - 45.6
LMA-S™	16.7	16.0	4.5	14.9 - 18.6
LTS-D™	19.4	19.0	3.4	18.0 - 20.8
Attempts required for successful insertion (no.)				
Macintosh	1.0	1.0	0.0	-
Airtraq®	1.2	1.0	0.4	1.0 - 1.3
LMA-S™	1.0	1.0	0.0	-
LTS-D™	1.0	1.0	0.2	1.0 - 1.2
Device difficulty rating (Scale 1 -10)				
Macintosh	3.7	3.5	2.0	2.9 - 4.5
Airtraq®	4.5	4.0	2.0	3.7 - 5.3
LMA-S™	1.7	1.0	1.0	1.2 - 2.1
LTS-D™	2.5	2.0	1.7	1.8 - 3.2

LMA-S™, Laryngeal Mask Airway - Supreme™; LTS-D™, Laryngeal Tube Suction - Disposable™

5.2.1.1 Participants' Demographic Information

Descriptive statistics were calculated for participant demographics. Of the 26 paramedics, 23 (88%) completed the National Diploma in Ambulance and Emergency Care or Emergency Medical Care, and three (12%) completed the Bachelor of Technology Degree in Emergency Medical Care. All participants had previously practiced with the Laerdal ALS Simulator® manikin during their paramedic training or thereafter. The mean operational paramedic experience of the participants at the time of data collection was 38.8 months (CI [0.95]; 22.1 - 55.5), while the mean self-estimated number of entrapment-trauma airway management per year was 4.3 (CI [0.95]; 2.8 - 5.8). Figures 5.1 and 5.2 illustrate the operational paramedic experience and yearly entrapment-trauma airway management estimates respectively.

All paramedics (100%) are equipped with Macintosh laryngoscopes when performing their operational duties and one participant (3.8%) indicated having access to the LTS-D™ as an airway device option. As other devices, 18 (69.2%) participants carry standard LMAs in their kit and four (15.4%) have the Igel®.

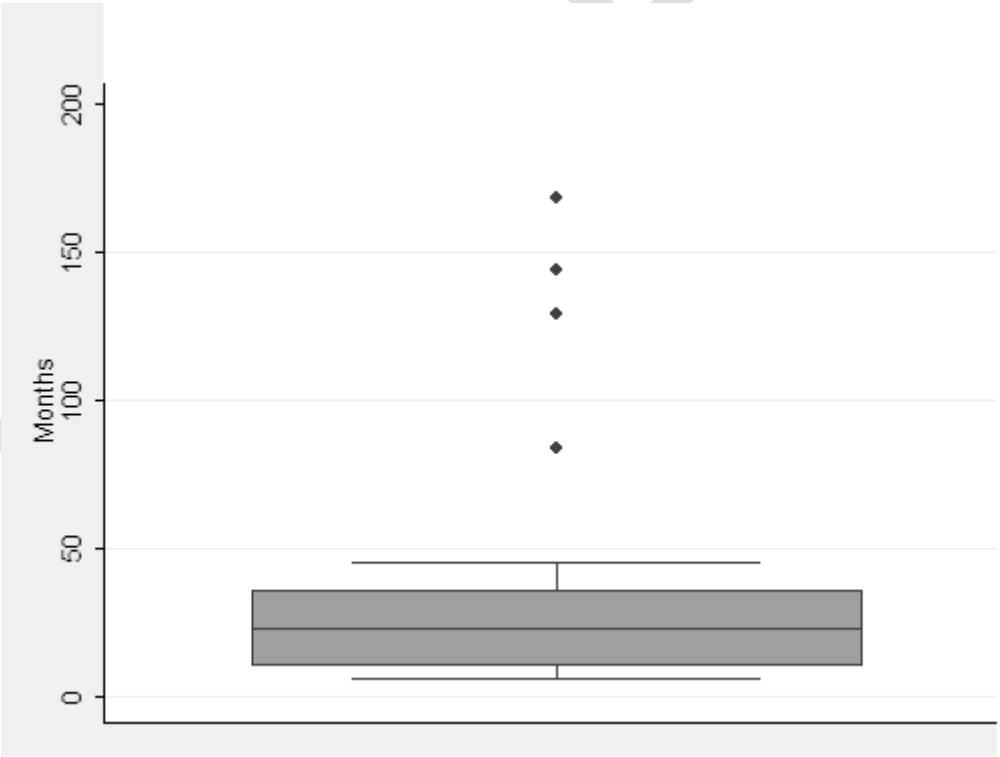


Figure 5-1: Box-plot graph illustrating the paramedics' operational experience in months.

The mean number of months was 38.8 (CI [0.95]; 22.1 - 55.5), however, due to several high outliers the median number of months is important to note. This value was 23 months.

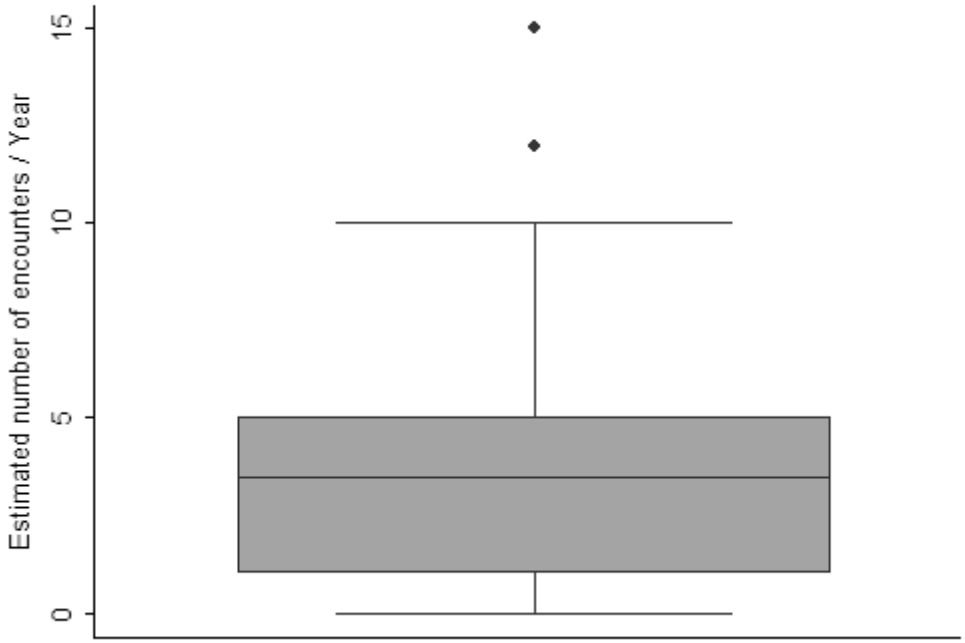


Figure 5-2: Box-plot graph illustrating the paramedics' estimate of how often per year they are faced with airway management of the entrapped patient.

5.2.1.2 Time to First Ventilation

Endotracheal intubation using the Macintosh laryngoscope took a mean time to first successful ventilation of 37.7 seconds (CI [0.95]; 31.8 - 43.5) and by indirect laryngoscopy using the Airtraq® 41.2 seconds (CI [0.95]; 36.7 - 45.6). The LMA-Supreme™ was found to have the shortest mean time to first successful ventilation with 16.7 seconds (CI [0.95]; 14.9 - 18.6), closely followed by the LTS-D™ with 19.4 seconds (CI [0.95]; 18.0 - 20.8). This is graphically illustrated in Figure 5.3.

To determine if the differences between the above mentioned findings are significant, the following tests were conducted: A Kruskal-Wallis Test was performed and the result indicated that the observed difference between the four devices with respect to time to first successful ventilation is indeed statistically significant (p<0.001). There was also a distinct difference observed between the devices using ETI techniques as compared to SADs. Data were pooled into ETI (Macintosh & Airtraq®) and SAD (LMA-Supreme™ & LTS-D™) groups and the Wilcoxon Rank Sum Test was used to determine statistical significance. The result indicates that SADs had a significantly faster time to first

successful ventilation as compared to ETI devices (p<0.001). Similar tests were conducted within the ETI and SAD groups. The results indicate that the Macintosh and Airtraq® are not significantly different in terms of time to first successful ventilation (p=0.17), however, the observed difference between the LMA-Supreme™ and LTS-D™ is statistically significant (p=0.003) in favour of the LMA-Supreme™.

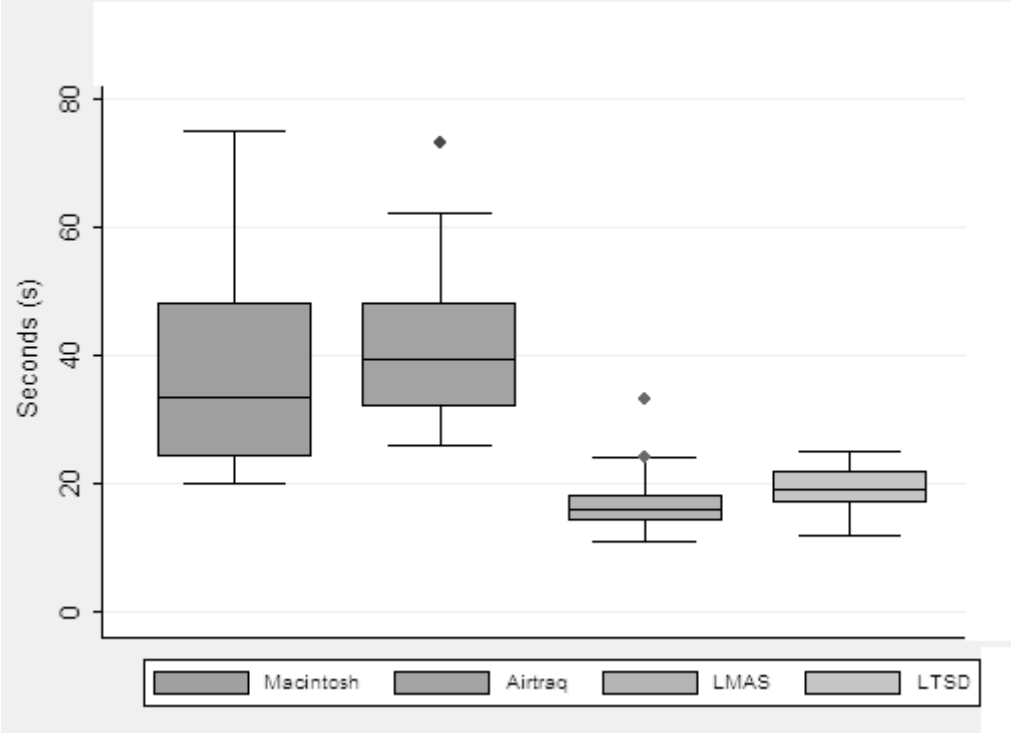


Figure 5-3: Box plot graph illustrating time to first successful ventilation with the four airway devices.

LMA-S™, Laryngeal Mask Airway - Supreme™; LTS-D™, Laryngeal Tube Suction - Disposable™

5.2.1.3 Placement Success

Both face-to-face intubation with the Macintosh laryngoscope and the insertion of the LMA-Supreme™ had 100% first-attempt success. Five participants required a second attempt to successfully intubate the manikin using the Airtraq® and one participant had to re-insert the LTS-D™ because the first insertion resulted in tracheal intubation. These results are tabulated in table 5.2. Thus, the Airtraq® required a mean 1.2 attempts (CI [0.95]; 1.0 - 1.3) for successful placement. Even though the mean number of attempts remained at 1.0 (CI [0.95]; 1.0 - 1.2) for the LTS-D™, attention is drawn to the standard deviation of 0.2 resulting from the one oesophageal placement.

To determine if the variation in first-attempt success rate was statistically significant depending on the device, a Chi-Square Test was performed. First-attempt success was 100%, 81%, 100%, and 96% for the Macintosh, Airtraq®, LMA-Supreme™, and LTS-D™ respectively. The results of the performed test indicated that the difference in first-attempt success are indeed statistically significant (p=0.007), however, this difference arises purely from the lower first attempt success rate of the Airtraq®.

Table 5-2: Number of participants successfully placing device per attempt

Device	1st Attempt	2nd Attempt	3rd Attempt
Macintosh	26	-	-
Airtraq®	21	5	-
LMA-Supreme™	26	-	-
LTS-D™	25	1	-

LMA-S™, Laryngeal Mask Airway - Supreme™; LTS-D™, Laryngeal Tube Suction - Disposable™

5.2.1.4 Rated Degree of Difficulty

Face-to-face intubation using the Macintosh laryngoscope was rated a mean 3.7/10 (CI [0.95]; 2.9 - 4.5) with one being least difficult and ten being most difficult. The Airtraq® was rated most difficult with a mean score of 4.5/10 (CI [0.95]; 3.7 - 5.3). The LMA-Supreme™ was the device generally rated least difficult to insert with a mean score of 1.7/10 (CI [0.95]; 1.2 - 2.1). The LTS-D™ has mean score of 2.5/10 (CI [0.95]; 1.8 – 3.2). Figure 5.4 shows these findings graphically as box-plots.

Analysis was done to establish if the observed difference between rating score between all four devices was statistically significant. Data were assumed to be ordinal and not normally distributed. A Kruskal-Wallis Test was performed to determine significance and the results indicated that between the four groups there is a statistically significant difference in observed rating score (p<0.001).

Next data were once again pooled into an ETI group and a SAD group and analysed to see if the difference between these two groups in terms of rating of insertion difficulty is statistically significant. A Wilcoxon Rank Sum test was performed which indicated that there is a statistically significant difference with SAD being rated easier to insert (p<0.001). Furthermore, the mean rating score within the above mentioned groups was assessed. The Wilcoxon Rank Sum Test indicated no statistically significant difference between the Macintosh and the Airtraq® (p=0.20), however, the test did show a statistically significant difference between the LMA-Supreme™ and the LTS-D™ (p=0.02).

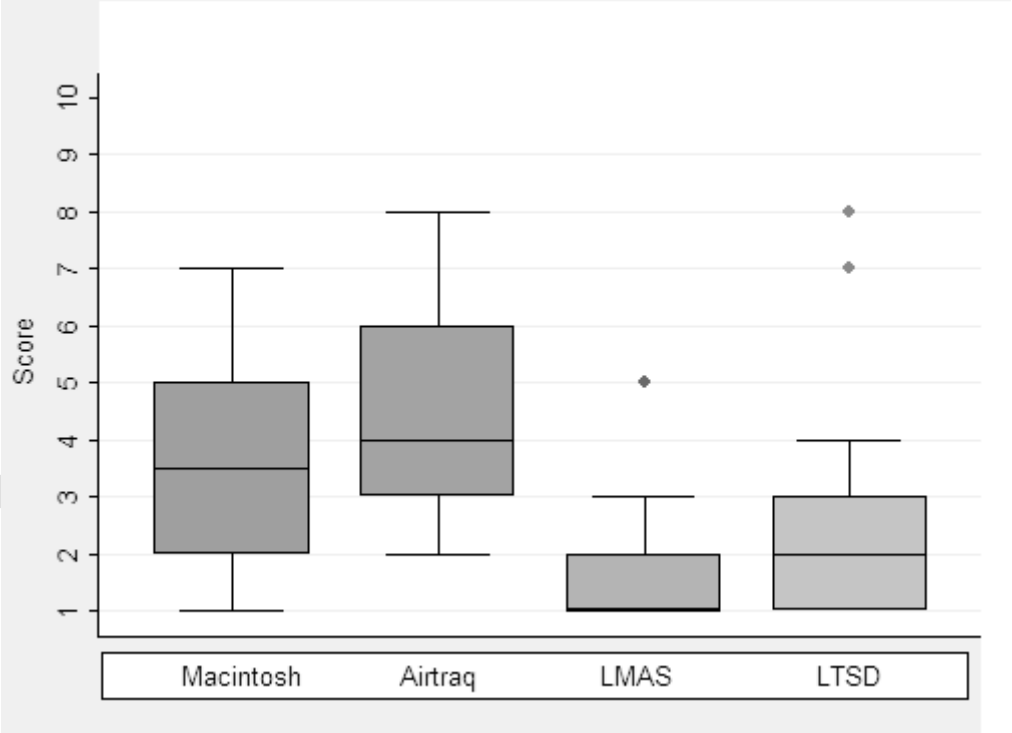


Figure 5-4: Box plot graph illustrating rated degree of insertion difficulty of the four airway devices.

LMA-S™, Laryngeal Mask Airway - Supreme™; LTS-D™, Laryngeal Tube Suction - Disposable™

The view of airway structures graded as per Cormack and Lehane during endotracheal intubation with the Macintosh and Airtraq® laryngoscopes is illustrated as a column chart in figure 5.5. For intubation with the Macintosh versus Airtraq® laryngoscopes CLG I was recorded 12 vs. 21 times (46.2% vs. 80.8%); CLG II 13 vs. 5 times (50.0% vs. 19.2%); and CLG III 1 vs. 0 times (3.8% vs. 0.0%). CLG IV view was not recorded for any of the two devices.

To compare the perceived degree of difficulty rating with the Cormack Lehane grade, a Spearman Rho Test was conducted for the entire endotracheal group (pooled data) which indicated that a relationship does exist between perceived degree of difficulty rating and CLG which is statistically significant. Subsequently a Spearman Rho Test was conducted per device and the results indicate that for the Macintosh there is an association (Spearman's rho = 0.5020; 50% of variation in difficult grading explained by variation in CLG) which is statistically significant (p=0.01). The results for the Airtraq® indicate that there is no statistically significant relationship between difficulty rating and CLG (p=0.28). Figure 5.6 suggests these findings graphically by contrasting the finding of the two variables as box-plots.

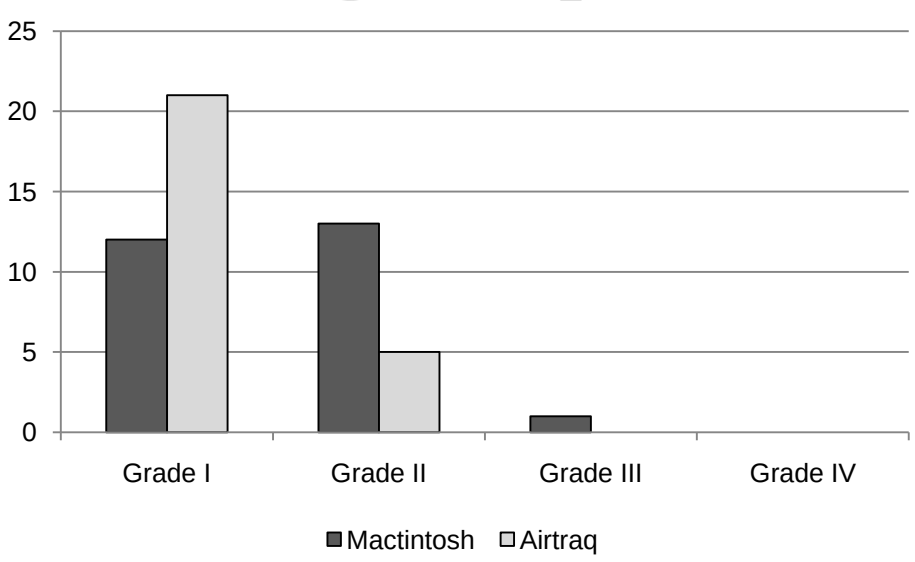


Figure 5-5: Column chart illustrating number of CLG views with Macintosh compared with Airtraq® laryngoscopes.

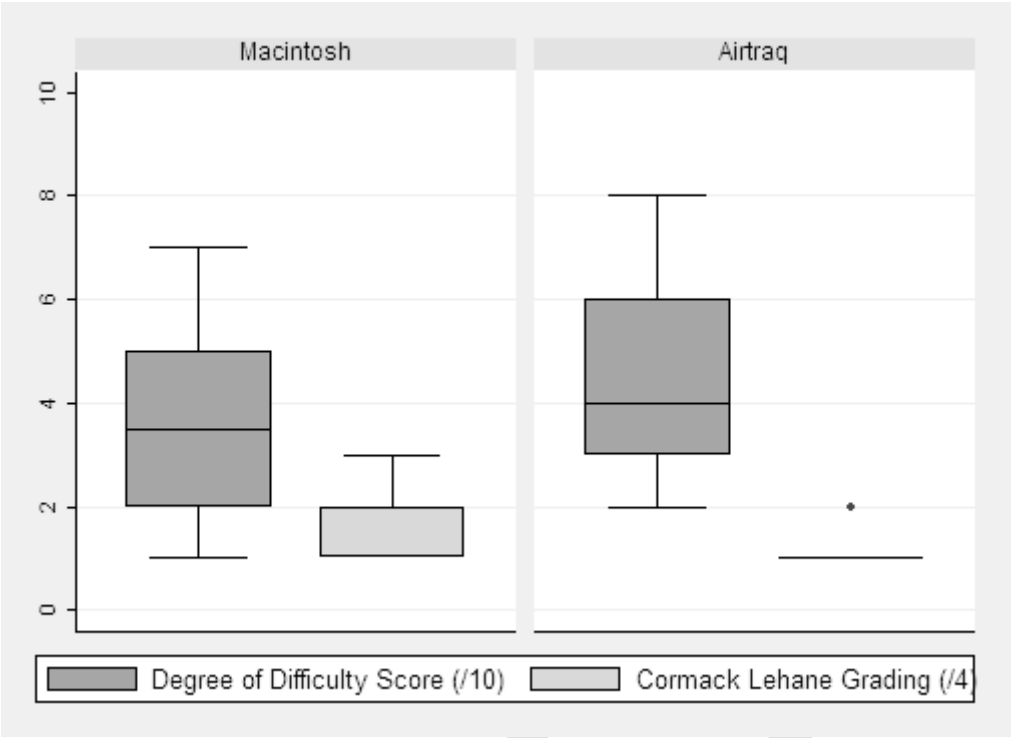


Figure 5-6: Box plot graph comparing rated degree of difficulty for ETI devices to Cormack-Lehane grading.

5.2.2 Multiple Regression Analysis

In order to correlate rated degree of difficulty with time to first ventilation and number of attempts required for successful placement, multiple regression analysis was performed. This means that the rated degree of difficulty remained a dependent variable and was analysed to examine if this measure may truly be explained by time to first ventilation and number of attempts required for successful insertion. The latter two thus became predictor variables.

Multiple regression analysis was performed using an automatic forward stepwise model to determine if rated degree of difficulty was associated to the time to first ventilation variable as well as the number of attempts required for successful placement variable. The results of the test indicates that there is a statistically significant association (Adjusted R^2 = 0.4311, p<0.001) between rated degree of difficulty and time to first ventilation (p< 0.001; CI [0.95]; 0.06 to 0.10) as well as between rated degree of difficulty and number of attempts (p<0.001; CI [0.95]; 1.32 to 3.90).

Table 5-3: Multiple Regression Analysis: Rated degree of difficulty

Predictor Variable	***b***	**SE**	***t***	**95% CI**	***p* value**
Time to first successful ventilation	0.08	0.01	7.38	0.06 - 0.10	<0.001
Attempts required for successful insertion	2.61	0.65	4.02	1.32 - 3.90	<0.001
Constant	-1.92	0.73	-2.64	-3.37 - -0.48	0.01

N of obs. = 104 airway placements

F = 40.03 R^2 = 0.44 Adjusted R^2 = 0.43

As part of the analysis, it was also investigated whether paramedic experience or the estimated number of entrapment-trauma airway management had any association with time to first ventilation, number of attempts required for successful placement, or rated degree of insertion difficulty. This was performed in order to identify whether either of these two attribute variables could possibly be confounders.

Using a multiple regression analysis the association between paramedic experience in months and the above-mentioned variables was performed. The results indicated that

there is no significant association (adjusted R^2 = 0.0119, p=0.24) overall or between any of the dependent variables with regards to paramedic experience. The same model was then repeated for estimated number of entrapment-trauma airway management. Similarly, no significant association was found (Adjusted R^2 = -0.0132; p=0.65) overall or between the individual variables. When this was repeated by device, for all devices in both models no association was found.

5.3 Qualitative Data

5.3.1 Reasons for Ratings of Degree of Insertion Difficulty

Most participants who graded face-to-face intubation with the Macintosh laryngoscope as less difficult did so because of “sufficient experience” (11/26). Another frequent reason given for low difficulty scores for endotracheal intubation with the Macintosh laryngoscope included “type of equipment” (9/26) also suggesting that using the standard tool for ETI is an acquainted skill amongst many participants. “Simulated patient anatomy” was also commonly noted (8/26). Paramedics who found face-to-face intubation with the Macintosh laryngoscope relatively difficult did so predominantly because of “lack of experience” (8/26) in combination with “patient position” (8/26). As ETI with the Macintosh laryngoscope is standard practice for all paramedics, “lack of experience” indicates unfamiliarity with performing the technique in a seated patient with frontal access, i.e. “lack of experience” is closely linked to “patient position” and “practitioner position”, the latter of which was noted only three times (3/26). Only three participants recorded “access to the patient” as reasons for high difficulty scores.

Those few participants, who rated the Airtraq® relatively easy, did so mostly because of “type of equipment” (6/26) and the simulated airway anatomy (4/26). The Airtraq® was generally rated the most difficult device to use as show in section 5.2.1.4. Reasons given for rating the device relatively difficult were predominantly “lack of experience” (15/26) and “type of equipment” (13/26). “Patient position”, “practitioner position” and “access to patient” was recorded six, six, and two times respectively.

The reason why the LMA-Supreme™ was overall rated the least difficult device to insert was almost exclusively due to the “type of equipment” (23/26). Those few outlying participants who found it relatively difficult to insert noted “Lack of experience” (1/26), “simulated airway anatomy” (1/26), and “type of equipment” (1/26) as the reasons. Similarly, the simplicity of the LTS-D™, i.e. “type of equipment” was the dominant reason for its comparatively easy insertion (17/26). Those participants, who had relative difficulty with insertion of the LTS-D™, attributed it to “lack of experience” (3/26), “patient position” (2/26), “practitioner position” (2/26), “access to patient” (2/26), and “type of equipment” (2/26). The leading reasons for relatively easy and difficult insertion are listed in table 5.4 below.

Table 5-4: Leading reasons for perceive degree of insertion difficulty

	Easy	Difficult
Device		
Macintosh	Sufficient experience	Lack of experience and patient position
Airtraq®	Type of equipment	Lack of experience
LMA-S™	Type of equipment	Lack of experience , simulated airway anatomy, type of equipment
LTS-D™	Type of equipment	Lack of experience

LMA-S™, Laryngeal Mask Airway - Supreme™; LTS-D™, Laryngeal Tube Suction - Disposable™

5.3.2 Device Preferences and Reasons

5.3.2.1 Device Preferences

When participants were asked which device they preferred, most of them chose the Macintosh laryngoscope for ETI (10/26; 38%). This was followed very closely by the LMA-Supreme™, which nine participants identified as their preferred device (9/26; 35%). Five paramedics marked the Airtraq® as their preference (5/26; 19%) and only two participants would select the LTS-DTM as their favoured airway device (2/26; 8%). Figure 5.7 illustrates these preferences amongst the participating paramedics as a pie chart.

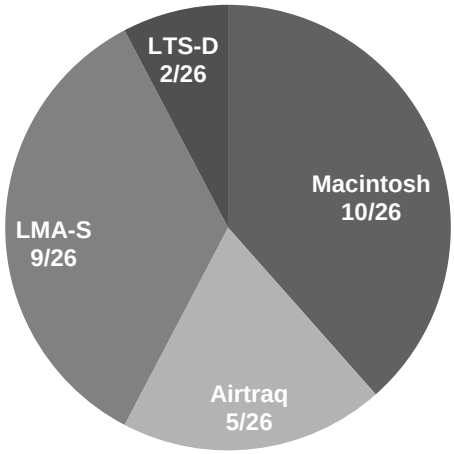


Figure 5-7: Distribution of participants' preferred airway device

LMA-S™, Laryngeal Mask Airway - Supreme™; LTS-D™, Laryngeal Tube Suction - Disposable™

5.3.2.2 Reasons for Device Preferences

The most frequent reasons and comments from the participants are listed in table 5.5 below. Most paramedics who preferred the Macintosh laryngoscope did so because of their clinical experience with this specific laryngoscope (9/10). Further common reasons were based on the advantages an endotracheal tube offers compared to a SAD.

Paramedics who preferred the Airtraq® base their choice on the improved visualisation capabilities of indirect laryngoscopy. Besides “seeing the position of the tube” (4/5), several participants commented on the improved laryngoscopy. “Enables visualising the complete airway with less effort than Macintosh laryngoscope” (participant 23). “Easy and clear visualisation of the glottic opening” (participant 28). Two participants also recognised less cervical spine movement during intubation with the Airtraq® and added this to their motives for choosing the device.

Rationale for preferring both SAD was predominantly the “faster insertion time” (LMA-Supreme™: 9/9; LTS-D™: 1/2). All paramedics who favoured the LMA-Supreme™ also did so because of less cervical spine movement, once again not an exclusive property of the specific device. The ease of insertion was noted for both devices by several participants too: “Ease of insertion” (participant 29); “Easier to insert” (participant 14).

Table 5-5: Participants' reasons for preferred airway devices

Preferred Device	Most frequent reasons and comments
Macintosh	• Clinical Experience • Seeing the position of the tube • Decreasing the likelihood of aspiration • Stability of the device after insertion • "ETI as definitive airway. Others as rescue devices"
Airtraq®	• Seeing the position of the tube • Decreasing the likelihood of aspiration • Less cervical spine movement • "Improves view/ CLG" • "Enables visualising the complete airway with less effort than Macintosh laryngoscope" • "Airtraq is very easy and simple to use" • "Easy and clear visualisation of the glottic opening"
LMA-S™	• Faster insertion time • "Ease of insertion"
LTS-D™	• Faster insertion time • "Easier to insert" • "Smaller"

LMA-S™, Laryngeal Mask Airway - Supreme™; LTS-D™, Laryngeal Tube Suction - Disposable™

5.4 Conclusion

This chapter presented the results that were produced by analyses of raw quantitative and qualitative data. Descriptive information of the study participants was examined. Specified statistical testing has provided evidence of significant differences between many variables measured during data collection. The perceptions of participants were organised into major themes, identifying reasons for degree of insertion difficulty ratings as well as the participants' preferred airway devices and their rationale behind this. The following chapter will interpret these findings.

CHAPTER 6 - DISCUSSION

6.1 Introduction

In this final chapter, the major findings of the research are stated and the research findings are construed in light of the knowledge base formed by the previous chapters. The chapter's aim is to answer the research question, relating the findings to similar studies, and considering clinical relevance. Limitations are identified including an acknowledgment of the generalisation margins. The chapter brings the report to a close with a final conclusion and suggestions for further research.

6.2 Major Findings

6.2.1 Time to First Ventilation

To recall, the objective was to determine which airway device has the shortest time to successful ventilation in the simulated entrapped patient with restricted access. In this study, the LMA-Supreme™ had significantly faster time to first successful ventilation than any of the other airway devices in the simulated entrapped patient with restricted access. On average, the LMA-Supreme™ was inserted 21 seconds faster than the endotracheal tube with the Macintosh laryngoscope, 24 seconds faster that the endotracheal tube with the Airtraq®, and three seconds faster than the LTS-D™.

6.2.2 Placement Success

To recall, the objective was to determine which airway device has the highest success rate (i.e. attempts required for correct placement) in the simulated entrapped patient with restricted access. In this study, LMA-Supreme™ insertion and endotracheal tube insertion with the Macintosh laryngoscope was achieved with a 100% first-attempt success rate in the given simulated scenario. First-attempt success rate with the Airtraq® was significantly lower in this study and one tracheal insertion of the LTS-D™ indicated that this is a possible misplacement at least in the human simulator.

6.2.3 Rated Degree of Insertion Difficulty

To recall, the objective was to determine which airway device is perceived to be the least difficult to insert in the simulated entrapped patient with restricted access. In this study, both SADs were perceived to be significantly less difficult to insert compared to endotracheal tube insertion with either of the two ETI devices. The main reason for this was the type of equipment, i.e. the relative ease of blind SAD insertion. The LMA-Supreme™ was rated to be the overall least difficult to insert by participants, even though not significantly less difficult than the LTS-D™. Although rated as the most difficult device, the Airtraq® has clear advantages in providing better laryngoscopy. More experience with the Airtraq® may decrease the perceived degree of difficulty in increase first-attempt success.

6.2.4 Correlation of Rated Degree of Difficulty with Time and Success Rate

To recall, the objective was to correlate rated degree of difficulty with time and success rate. In this study, analyses indicated that the rated degree of difficulty was associated with time to first ventilation as well as the number of attempts required for successful placement, strengthening the research findings.

6.2.5 Analyses of Participants' Perceptions

To recall, the objective was to analyse the perceptions participants have about the airway devices used in the simulated entrapped patient with restricted access. In this study, despite disadvantages in terms of time and skill requirements, ten participants preferred placement of an endotracheal tube with the Macintosh laryngoscope. This preference is very closely followed by the LMA-Supreme™ preferred amongst nine participating paramedics.

The main reasons for ETI with the Macintosh laryngoscope being a first choice are the participants' clinical experience with the Macintosh laryngoscope and the advantages of an endotracheal tube over a SAD. Those participants who chose the LMA-Supreme™ as their preferred device did so mainly because of its advantages in insertion time.

6.2.6 Research Question

To recall, the research question was:

> Which advanced airway device can be inserted the fastest and most reliably by paramedics in the simulated entrapped patient?

In light of the results, it can be said that in this study the LMA-Supreme™ was the airway device that could be inserted the fastest and most reliably by paramedics in the simulated entrapped patient. Even though statistically significantly slower compared to the LMA-Supreme™ and rated more difficult, face-to-face ETI with the Macintosh laryngoscope can also be regarded as a reliable advanced airway option in the entrapped patient considering placement success and the paramedics' preferences which were based primarily on clinical experience with the laryngoscope.

6.3 Interpretation and Clinical Relevance

6.3.1 Supraglottic Airway Devices in the Entrapped Patient

This study illustrates that both SADs, the LMA-Supreme™ and the LTS-D™, are feasible alternatives to ETI in the entrapped patient after a MVC as evidenced by the advantages in time and ease of insertion. Many of the participating paramedics indicated the LMA-Supreme™ as their preferred device for the entrapped patient requiring airway interventions. When compared to the Airtraq®, the SADs also led in terms of success rate. These findings echo the results of similar manikin studies by Polk, *et al*. (2001:21-22) as well as Hoyle, *et al*. (2007:330-336) who also report advantages of SADs over ETI in terms of identical variables and similar simulated restricted access scenarios. Findings that these SADs have a high success rate after only short training are also replicated in this study.

6.3.1.1 Supraglottic Airway Devices as an Alternative to Endotracheal Intubation

Prehospital intubation can be, and very often is, significantly different to intubation performed in the controlled setting of the hospital as described in the introduction. This is especially true in cases where access to the patient is restricted. Both endotracheal intubation devices, the Macintosh laryngoscope and the Airtraq® optical laryngoscope, were rated significantly more difficult compared to SAD insertions in this study. The first-attempt success rate of the Airtraq® was significantly lower than any of the other devices. Conversely to the 100% first-attempt success rate of ETI with the Macintosh laryngoscope in this manikin study, many investigations of prehospital intubation success rates find these to be sub-optimal. The potential implications of low ETI success in the prehospital setting often provides ground for heated debate on the safety and efficacy of the procedure performed in this environment.

Hubble and co-researcher (2010:377-401) recently published findings from their large-scale, international meta-analysis of prehospital airway control techniques. Overall success rate of oral ETI is reported to be 86.5% (CI [0.95]; 83.3-89.2), with all non-physicians reaching a success rate of 86.3% (CI [0.95]; 82.6-89.4) (Hubble, *et al*. 2010:385). Some of the lowest success rates are reported in trauma patients. Amongst all clinicians the success rate for oral ETI in trauma patients is 73.7% (CI [0.95]; 62.6-82.5). Oral ETI performed by non-physicians in trauma patients achieved a success rate of only 69.8% (CI [0.95]; 60.1-78.0) (Hubble, *et al*. 2010:385). The analysis does not appear to

take patient position and access into consideration but shows clearly that, especially for trauma patients, oral ETI (without RSI) has relatively low success rates.

Findings of the case series by Hulme and Perkins (2005:743) allude to an ETI success rate of 73% in entrapped patients. The large number of studies critical of prehospital ETI together with the evolution of SADs has even led some authors to predict the possible disappearance of this skill in most EMS systems (Bledsoe & Gandy, 2009:88-99). In line with this, Southard, Braude and colleagues (2010:576-578; 2010:1217; 2007:250-252) explore and advocate Rapid Sequence Airway (RSA), a new airway management technique in which the preparation and pharmacology of RSI is paired with intentional placement of a SAD without prior attempt at endotracheal intubation.

BVM ventilation, which before the advancement of SADs was the only non-surgical alternative to ETI, is a basic yet challenging skill especially in the patient with restricted access. A high potential of achieving only inadequate face-mask seal and significant leak causing insufficient lung ventilation exists (Genzwürcker, *et al*. 2007:164). Additionally the risk of gastric insufflation is high (von Goedecke, *et al*. 2006:70-79). SADs are able to provide more effective ventilation than the BVM (Alexander, *et al*. 1993:231-234; Asai, Murao & Shingu, 2000:1099-1102; Genzwürcker, *et al*. 2007:164).

The patient's needs are primarily oxygenation and ventilation which calls for an oxygenation/ventilation-focused airway management rather than intubation-focused airway management. The entrapped patient with restricted access presents with a difficult airway and potentially the need for fast oxygenation and ventilation. Time delays to initiate oxygenation and ventilation by ETI attempts can put the patient at risk of hypoxaemia and hypoxia as well as airway trauma (Byhahn & Dörges, 2007:482-483). In their review, Cook and Hommers (2006:371-387) remind us that "...unrecognized oesophageal intubation and ventilation will result in death, perhaps of someone who would have otherwise survived. Aspiration, although an important consideration, is not universally fatal and therefore avoidance of aspiration is a lesser priority than establishing a clear airway."

Furthermore, Genzwürcker (2011:1) argues that at the time of intervention, aspiration has already occurred in a significant portion of patients, so that the aspect of airway protection is important, but subordinate in comparison to ensuring adequate oxygenation.

6.3.1.2 Limitations in Airway Protection

The concern of an increased aspiration risk remains and many of the participants who preferred either of the two laryngoscopes over the SADs did so because of the superior airway protection capability of an endotracheal tube. However, despite being inferior to in terms of airway protection ability, newer SADs may be able to provide better protection by improved oesophageal seal formation than the classic LMA without gastric drainage.

Bercker, *et al*. (2008:445-448) explored the seal provided by seven SADs during increased oesophageal pressure in cadavers. The study included amongst others the Laryngeal Tube Suction II™ (LTS II™), a re-usable version of the laryngeal tube with gastric drainage, as well as the LMA-Classic™ and LMA-ProSeal™. The LMA-Supreme™ is similar to the LMA-ProSeal™ in that both feature an elongated mask and a gastric drainage tube. However, the LMA-Supreme™ lacks the additional posterior cuff that pushes the mask of the LMA-ProSeal™ against the periglottic tissue. Airway leak pressures of these two particular LMAs have, nevertheless, been shown to be similar (Eschertzhuber, *et al*., 2009:79-83; Hosten, *et al*., 2009:852-857). Bercker and colleagues (2008:445-448) showed that by losing its seal at an oesophageal pressure of 48 cmH_2O, the LMA-Classic™ had significantly poorer oesophageal seal than all other SADs tested in their study. With clamped drainage tubes, the LTS II™ and LMA-ProSeal™ were able to withstand an oesophageal pressure of 74 cmH_2O and 71 cmH_2O respectively and drained water at a maximum pressure of 130 cmH_2O without any tracheal aspiration when the oesophageal drainage tube was open (Bercker, *et al*., 2008:447). Considering that oesophageal pressure may rise as high as 105 cmH_2O during vomiting (Brimacombe & Keller, 2006:328), the importance of using devices with drainage tubes becomes obvious.

6.3.2 Endotracheal Intubation in the Entrapped Patient

6.3.2.1 Face-to-Face Endotracheal Intubation with the Macintosh Laryngoscope

Even with significant developments in the field of emergency airway management, endotracheal intubation is widely considered to remain the gold standard in securing the airway. Despite being rated on average to require more skill and time, face-to-face insertion of an endotracheal tube with the Macintosh laryngoscope was the most preferred way of securing the patient's airway in this study. In addition to the comfort that clinical experience created to apply this skill with high success, the attributes of an endotracheal tube contributed to this prevailing preference. Not only does the endotracheal tube provide unsurpassed airway protection from aspiration, but also allows for ventilation even at high airway pressures, offers a route for endotracheal drug administration, and a means to perform tracheal suctioning (Dörges, 2005:706). Many responses from participants in this study seemed to echo the sentiment of Bernhard, *et al*. (2004:892) who support that the endotracheal tube still offers unmatched features and needs to remain the definitive airway that can be established prehospitally, especially for the trauma patient.

The increasing availability of SAD should not lead to the avoidance of endotracheal intubation or de-emphasise the importance of prehospital providers having and maintaining the competence to insert an endotracheal tube should the patient's needs demand this (Bernhard, *et al*., 2004:892), e.g. thoracic trauma requiring high airway pressures for effective ventilation.

6.3.2.2 ETI by Indirect Laryngoscopy with Airtraq in the Entrapped Patient

The incidence of unsatisfactory view of the larynx during prehospital airway management is high when compared with intubations performed in the operating theatre. Timmerman, *et al*. (2006:179-185) report CLG III view in 13% vs. 5%, and CLG IV view in 7% vs. 1% respectively. Together with difficult laryngoscopy (42.7%), position of the patient (48.8%) was reported to be the leading cause of difficult airway management in this prospective observational study of prehospital airway interventions by anaesthesia-trained physicians (Timmerman, 2006: 179-185).

The response to a difficult intubation situation requires forethought and planning (Kovacs, *et al*., 2005:92). To execute management of the difficult airway more effectively and safely, several different alternative intubation devices have been developed. Flexible fibreoptic intubation is a milestone in this field and has internationally established itself as

a standard *in-hospital* approach to the anticipated difficult airway (Noppens, Werner & Piepho, 2010:149). However, acquisition and maintenance of these devices are expensive and they presently are unrealistic options in prehospital emergency medicine especially in developing countries. With the development of optical-, digital-, and video-technology in recent years, new laryngoscopes have nevertheless been invented, that pose as reasonable alternatives even in the prehospital setting. Without the need for axes alignment, indirect laryngoscopy can provide a high-grade view of the glottic opening and do so with significantly less cervical spine movement (Turkstra, Pelz & Jones, 2009:97-101).

In this study, the Airtraq® enabled CLG 1 view in nine more participants than the Macintosh laryngoscope and CLG II and III view was experienced less frequently with the Airtraq® than with the Macintosh laryngoscope. These findings replicate the findings of improved laryngoscopy by Harvey, *et al*. (2010:S70). Even though not a measure of this study, several participants appear to have noticed less cervical spine movement when intubating with the indirect laryngoscopy device, noting this a reason in support of the Airtraq® as their preferred device.

Albeit the lowest first-attempt success rate in this study, the overall 100% success rate with no more than two attempts suggests a steep learning curve as found by Hirabayashi and Seo (2009:112-113) as well as Wallard and co-researcher's (2008: 26-31). However, results indicating superiority of the Airtraq® over the Macintosh laryngoscope in terms of first-attempt success in the simulated entrapped patient with restricted access are not re-produced in this study.

6.4 Limitations

6.4.1 Simulation

One obvious limitation of this study is that it was performed on a manikin in a simulated entrapment scenario. This limitation cannot duplicate a real incident exactly. The mock patient had no airway reflexes or movement and was apnoeic. No vomiting or oropharyngeal haemorrhage was present, which is a frequent occurrence in a real patient in this situation. The vehicle was not damaged or deformed. Nevertheless, use of the manikin and vehicle allowed standardisation of the patient, airway characteristics, as well as the surrounding across all participants and thus acted as constants rather than variables.

6.4.2 Sampling

The second major limitation of this study is the convenient/volunteer sampling strategy. This non-probability sampling results in limitations in generalising the research findings and introduced the potential for volunteer bias. In particular it needs to be highlighted that this limitation inhibits the generalisation of the finding that neither the months of operational experience nor the estimated level of exposure to airway management in entrapped patients had a significant association with performance in terms of success rates, time to first ventilation or rated degree of difficulty.

6.5 Final Conclusion and Suggestion for Further Research

The investigated SADs prove to be beneficial primary alternative and intermediate airway devices to be used by paramedics in the entrapped patient after a MVC. Both SADs could be placed quickly, easily and with high success with the LMA-Supreme™ being the fastest and least difficult to insert. Face-to-face endotracheal intubation with the Macintosh laryngoscope remains an important definitive airway that was shown to be performed competently by paramedics. The Airtraq® can be used for face-to-face ETI and enables improved laryngoscopy.

The results of this manikin study call for further evaluation of the LMA-Supreme™ and the LTS-D™ as SADs in emergency medicine and EMS. Primarily, this entails the assessment of the risk of aspiration and the ability to facilitate ventilation at increased airway pressures. Further investigation into the use of the Airtraq® is also warranted, especially as an alternative intubation device in the patients with anticipated difficult direct laryngoscopy.

CONFLICT OF INTEREST

The LMA-Supremes™ were supplied free of charge by The Laryngeal Mask Company Limited and the Airtraqs® by Teleflex Medical. The LTS-Ds™ were purchased from SSEM Mthembu Medical. None of the companies had any involvement in the workshop, data collection, or report write-up. The researcher is not in any way affiliated with any of the companies.

RESEARCHER'S PERSONAL NOTE

This research project presented an exceptional learning opportunity for which I am grateful. Conducting this research has taught me to prepare a robust research proposal with meticulous attention to detail, focus on the research aim, and careful consideration of ethical issues. Following my data collection protocol has made me realise the diligence and conscientiousness needed to produce high-quality data even when faced with unforeseeable challenges. Completion of the final report has demanded dedication and significantly improved my writing skills. I feel enriched by the many people who I have had the privilege of working and studying with during the course of this project and during research workshops. The combination of research methods was beneficial because it enabled me to gain insight into how the strengths from each of the two methods (quantitative and qualitative) can come together to form a comprehensive approach to find answers to research questions. I now feel enriched in my abilities to critically appraise research output as well as to identify problems requiring investigation to contribute to the ever-evolving evidence base of modern medicine, and I am aware and excited about how much more there is to contribute.

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ANNEXURES

MSc Med (Emerg Med) Research Project Gantt Chart										
	Conceptualisation	Literature Review	Write Research Proposal	Submit Research Proposal	Apply for Ethics Clearance	Data Collection	Data Analysis	Write Research Report	Proof Reading and Final Adjustment	Submit Research Report
2009										
Jan. 2010										
Feb. 2010										
Mar. 2010										
Apr. 2010										
May 2010										
Jun. 2010										
Jul. 2010										
Aug. 2010										
Sep. 2010										
Oct. 2010										
Nov. 2010										
Dec. 2010										
Jan. 2011										
Feb. 2011										
Mar. 2011										
Apr. 2011										
May 2011										
Jun. 2011										

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Mr Robin Pap

CLEARANCE CERTIFICATE	**M10606**
PROJECT	A Comparison of Airway Devices for the Stimulated Entrapped Patients
INVESTIGATORS	Mr Robin Pap.
DEPARTMENT	Department of Emergency Medicine
DATE CONSIDERED	26/06/2010
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 16/07/2010 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Dr C van Loggerenberg

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

Cape Peninsula
University of Technology

FACULTY: HEALTH & WELLNESS SCIENCES
Department: Emergency Medical Sciences
Contact: Ms N Deliwe (DeliweN@cput.ac.za)
Telephone: 021 953 8408 Fax: 021 959 6190

Ref: 184/NDEMCA/10
Date: 05 May 2010

To whom it may concern

RE: PERMISSION TO CONDUCT TRAINING WORKSHOP AND DATA COLLECTION FOR MSc MED RESEARCH

This serves to inform you that Mr Robin Pap a CPUT member of staff and registered at the University of Witwatersrand (student number 415487) has been granted permission to conduct the training workshops and data collections for his research on airway devices for the simulated entrapped patient at the facilities of the Department of Emergency Medical Sciences, CPUT during the 2010 academic year. We understand that this research forms part of his MScMed (Emerg Med) studies. This permission is subject to approval of the research by the relevant Wits Research Ethics Committee.

If you have any questions, please feel free to contact the Department at the contact details above.

Yours Sincerely

Mr LD Christopher
HOD: Emergency Medical Sciences

PO Box 1906 Bellville 7535 South Africa

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Mr R Pap
MScMed Student
University of the Witwaerstrand

26 July 2010

Dear Robin

A COMPARISON OF AIRWAY DEVICES FOR SIMULATED ENTRAPPED PATIENTS

Thank you for your presentation to the Divisional Research Committee in July. I am pleased to see that your research received Ethics Approval.
Permission is hereby granted to undertake your research in METRO EMS in the Western Cape.
This permission is valid for 6 months from the date of this letter.
Please do not hesitate to contact me if you require further information.

Kind regards

PROF LEE A WALLIS
MBChB MD DIMCRCSEd Dip Sport Med FRCSEd(A&E) FCEM FCEM(SA)
HEAD: EMERGENCY MEDICINE

A Comparison of Airway Devices in the Simulated Entrapped Patient

Dear Colleague

I am studying towards the Master of Science in Medicine at the University of the Witwatersrand and am doing a research project for completion of my degree. Research is the process to learn the answer to a question. In this research, I want to compare different airway devices that can be used by paramedics in the entrapped patient after a motor vehicle collision to learn which one is best to use. The seated position of the patient and restricted access may make airway management in general and endotracheal intubation (ETI) by direct laryngoscopy difficult. This may potentially result in failure to provide sufficient oxygenation and ventilation. Alternative intubation devices or intermediate supraglottic airway devices need to be considered.

There are numerous alternative airway devices, but the ones that I will be comparing to standard face-to-face intubation with the Macintosh laryngoscope are the Airtraq optical laryngoscope, the Laryngeal Mask Airway Supreme as well as the Laryngeal Tube Suction Disposable.

If you have recent operational experience as a paramedic (ideally 3 years), I hereby would like to invite you to take part in this research study. This will take place at the Department of Emergency Medical Sciences of the Cape Peninsula University of Technology (Bellville Campus) on four days. You can decide which of the days suits you best. There will be about ten participants per day.

Saturday, 04 September 2010, 09h00 – approx. 13h00
Monday, 06 September 2010, 09h00 – approx. 13h00
Saturday, 11 September 2010, 09h00 – approx. 13h00
Tuesday, 14 September 2010, 09h00 – approx. 13h00

You would participate in a brief practical workshop to train you in the devices and then would insert the devices in random order in a simulated entrapped patient. This will be video recorded. You would also be asked to complete a brief questionnaire which asks you to rate your perceived difficulty to insert the devices. There are no risks involved in this study and you would benefit from being able to learn about the different airway devices. Light refreshments will be served.

All data will be put together, analysed and the results presented to the rest of my class and possibly published in a research paper written for the scientific community. This publication

would be made available to you if you are interested. A number will be allocated to you and no names will be used on the data collection sheets. Efforts will be made to keep personal information confidential. Absolute confidentiality cannot be guaranteed. Personal information may be disclosed if required by law. Other than that, the individual results, including video footage, will not be made available to anyone without your expressed and written permission. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the Research Ethics Committee.

Participation is voluntary and you may discontinue participation at any time without penalty.

To enrol, please contact me on 082 4936326 or robin.pap@gmail.com

If you have any problems or complaints please contact the Wits Research Ethics Office:

Mrs Anisa Keshav
Wits Research Office
10th Floor Senate House
East Campus
Tel. 011 717 1234
Fax. 011 717 1265
e-mail anisa.keshav@wits.ac.za

Yours sincerely

Robin Pap

UNIVERSITY OF THE WITWATERSRAND
FACULTY OF HEALTH SCIENCES
DIVISION OF EMERGENCY MEDICINE

CONSENT TO ACT AS A PARTICIPANT IN RESEARCH

I, _____, being 18 years or older, consent to participate in a research project entitled:

AIRWAY DEVICES IN THE SIMULATED ENTRAPPED PATIENT

The procedures and questionnaires have been explained to me and I understand and appreciate their purpose, any risks involved, and the extent of my involvement. I consent to being video recorded during data collection. I have read and understand the attached information leaflet.

I understand that the procedures form part of a research project, and may not provide any direct benefit to me.

I understand that all experimental procedures have been sanctioned by the Research Ethics Committee, University of the Witwatersrand, Johannesburg.

I understand that my participation is voluntary, and that I am free to withdraw from the project at any time without prejudice.

_____ _____

Participant name and signature Date

_____ _____

Investigator name and signature Date

Participant Demographic Questionnaire

Participant No: _____

1. Please indicate your current highest qualification:

   ☐ Critical Care Assistant

   ☐ National Diploma: AEC or EMC

   ☐ Bachelor Degree in Technology: EMC

   ☐ Other (please specify _____)

2. Have you practiced with the Laerdal ALS Simulator® manikin during your paramedic training or thereafter.

   ☐ yes ☐ no

3. Please indicate how long you have been practicing as an operational paramedic and in which setting:

   Urban: _____ years, _____ months

   Rural: _____ years, _____ months

4. Please estimate how often you are confronted with airway management of the entrapped patient after a motor vehicle collision in your capacity as paramedic.

   Approximately _____ per year.

5. Please tick the advanced airway techniques/devices that you have at your disposal and use in your patient management:

   ☐ Laryngoscope with Macintosh blade
   ☐ Airtraq® optical laryngoscope
   ☐ Laryngeal Mask Airway Supreme®
   ☐ Laryngeal Tube Suction Disposable®
   ☐ Other (please specify)

   _____
   _____
   _____

A Comparison of Airway Devices in the Simulated Entrapped Patient
Workshop Plan

Overview and Purpose:	**Educational Standards:**
This workshop is designed for paramedics with pre-hospital airway management experience. The aim is to train individuals in airway devices under investigation, specifically the Airtraq® laryngoscope, the LMA Supreme®, and the Laryngeal Tube Suction Disposable®. The purpose of the workshop is to prepare all participants for research data collection as described in the research proposal.	Post-qualification didactic training workshop on advanced airway management

	Guide	**Material / Resources**
Objectives	• Describe the features of the airway devices. • List and explain the advantages and disadvantages of the airway devices. • Describe and demonstrate the steps of airway establishment using the airway devices. • Demonstrate to be cognisant of challenges in airway management in the seated entrapped patient after LMVC. • Describe and demonstrate the steps of airway establishment using the airway devices in the simulated entrapped patient.	• Notebook • Media Projector • Skills Lab. 2 • LMV & gazebo • Camera (x2)
Workshop Outline	1. Introduction 2. The Airway Devices: a. Macintosh Laryngoscope b. Airtraq Laryngoscope c. LMA Supreme d. LTS-D 3. Practical Airway Stations 4. The Entrapped Patient and Airway Considerations 5. Practical Airway Stations	
Followed by Light Refreshments and Data Collection Procedures		

Questionnaire Participant No:…….

Date ____/____/_____ Time: ____h____

Face-to-face ETI with laryngoscope with Macintosh blade:

1. To what extent were you able to visualise the larynx, epiglottis, and upper airway during this technique?

Cormack-Lehane Grade (please circle one):

1 2 3 4

2. How difficult did you find the ETI or ETI attempts?

Degree of difficulty (please circle one on the scale from 1 to 10):

Very easy Very difficult

1 2 3 4 5 6 7 8 9 10

3. Please mark one or multiple reasons for your rating:

- ☐ Sufficient experience
- ☐ Lack of experience
- ☐ Simulated patient airway anatomy
- ☐ Patient position
- ☐ Practitioner position
- ☐ Access to patient
- ☐ Absent external laryngeal manipulation
- ☐ Size of equipment
- ☐ Type of equipment

Questionnaire Participant No:…….

Date ____/____/_____ Time: ____h____

Face-to-face ETI with Airtraq® optical laryngoscope:

1. To what extent were you able to visualise the larynx, epiglottis, and upper airway during this technique?

Cormack-Lehane Grade (please circle one):

1 2 3 4

2. How difficult did you find the ETI or ETI attempts?

Degree of difficulty (please circle one on the scale from 1 to 10):

Very easy Very difficult

1 2 3 4 5 6 7 8 9 10

3. Please mark one or multiple reasons for your rating:

☐ Sufficient experience

☐ Lack of experience

☐ Simulated patient airway anatomy

☐ Patient position

☐ Practitioner position

☐ Access to patient

☐ Absent external laryngeal manipulation

☐ Size of equipment

☐ Type of equipment

Questionnaire Participant No:…….

Date ____/____/_____ Time: ____h____

LMA Supreme® Insertion

1. How difficult did you find the insertion or insertion attempts?

Degree of difficulty (please circle one on the scale from 1 to 10):

Very easy Very difficult

1 2 3 4 5 6 7 8 9 10

2. Please mark one or multiple reasons for your rating:

- ☐ Sufficient experience
- ☐ Lack of experience
- ☐ Simulated patient airway anatomy
- ☐ Patient position
- ☐ Practitioner position
- ☐ Access to patient
- ☐ Size of equipment
- ☐ Type of equipment

Questionnaire Participant No:…….

Date ____/____/_____ Time: ____h____

LTS-D® Insertion

1. How difficult did you find the insertion or insertion attempts?

Degree of difficulty (please circle one on the scale from 1 to 10):

Very easy Very difficult

1 2 3 4 5 6 7 8 9 10

2. Please mark one or multiple reasons for your rating:

- ☐ Sufficient experience
- ☐ Lack of experience
- ☐ Simulated patient airway anatomy
- ☐ Patient position
- ☐ Practitioner position
- ☐ Access to patient
- ☐ Size of equipment
- ☐ Type of equipment

Questionnaire Participant No:…….

Date ____/____/_____ Time: ____h____

Which device/technique do you prefer? (please mark one only)

- ☐ Face-to-face ETI with laryngoscope with Macintosh blade
- ☐ Face-to-face ETI with Airtraq® optical laryngoscope
- ☐ LMA Supreme® Insertion
- ☐ LTS-D® Insertion

Please give a reason or reasons for your preference:

- ☐ Clinical experience
- ☐ Seeing the position of the airway device in relation to the vocal cords.
- ☐ Decreasing the likelihood of aspiration
- ☐ Less cervical spine movement
- ☐ Faster time of insertion
- ☐ Stability of the device after insertion
- ☐ Other: _____
- ☐ Other: _____

A Comparison of Airway Devices for the Simulated Entrapped Patient

Data Collection Sheet

Participant No. ____ Date ____/____/_____ Time: ____h____

Face-to-face ETI with laryngoscope with Macintosh blade:

1. Time: _____min. _____sec. Successful ☐ Unsuccessful ☐
2. Time: _____min. _____sec. Successful ☐ Unsuccessful ☐
3. Time: _____min. _____sec. Successful ☐ Unsuccessful ☐

Face-to-face ETI with Airtraq® optical laryngoscope:

1. Time: _____min. _____sec. Successful ☐ Unsuccessful ☐
2. Time: _____min. _____sec. Successful ☐ Unsuccessful ☐
3. Time: _____min. _____sec. Successful ☐ Unsuccessful ☐

LMA Supreme® Insertion

1. Time: _____min. _____sec. Successful ☐ Unsuccessful ☐
2. Time: _____min. _____sec. Successful ☐ Unsuccessful ☐
3. Time: _____min. _____sec. Successful ☐ Unsuccessful ☐

LTS-D® Insertion

1. Time: _____min. _____sec. Successful ☐ Unsuccessful ☐
2. Time: _____min. _____sec. Successful ☐ Unsuccessful ☐
3. Time: _____min. _____sec. Successful ☐ Unsuccessful ☐